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PART II

ENVIRONMENTAL PROTECTION AGENCY

■

REGISTRATION OF PESTICIDES IN THE UNITED STATES

Proposed Guidelines; Economic Impact Analysis

[6560-10]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 162]

[FRL 960-4; OPP-30022A]

ECONOMIC IMPACT ANALYSIS

Proposed Guidelines for Registering Pesticides in the United States

AGENCY: Environmental Protection Agency (EPA), Office of Pesticide Programs.

ACTION: Publication of economic impact analysis relating to the proposed guidelines.

SUMMARY: The proposed guidelines for registering pesticides in the United States (hereafter referred to as "guidelines") were published in the FEDERAL REGISTER on July 10, 1978 (43 FR 29696). On page 29705 of that document, interested persons were advised that copies of the economic impact analysis developed in conjunction with subparts B, D, E, and F of the guidelines would be available upon request, However, in order to reach as wide an audience as possible, it has been decided to publish the entire text of the analysis in the analysis in the FEDERAL REGISTER. Comments are welcomed and will serve as input to the analysis for the guidelines when finalized. The comment period regarding the analysis has also been extended as indicated below; however, the comment period for the proposed guidelines (subpart B, D, and E) will terminate on September 8, 1978, published.

DATES: Comments concerning the economic impact analysis should be received on or before December 5, 1978.

ADDRESS: Written comments should be sent to the Federal Register Section, Office of Pesticide Programs (WH-569), EPA, Room 401, East Tower, 401 M Street SW., Washington, D.C. 20460. Comments should bear the identifying notation OPP-30022A, to distinguish them from comments on the proposed guidelines. All written comments will be available for public inspection in the office of the Federal Register Section at the address above from 8:30 a.m. to 4 p.m., Monday through Friday.

FOR ADDITIONAL INFORMATION CONTACT:

Gary Ballard, Office of Pesticide Programs (WH-568), EPA, Washington, D.C. 20460, 703-557-7335.

SUPPLEMENTARY INFORMATION: On July 10, 1978, the EPA published in the FEDERAL REGISTER three subparts of the guidelines: Subpart B, Introduction; Subpart D, Chemistry Requirements; and Subpart E, Hazard Evaluation: Wildlife and Aquatic Organisms. Subpart F, Hazard Evaluation: Humans and Domestic Animals, will be proposed shortly. These are the four subparts of the guidelines expected to generate significant economic impacts. Two other subparts to be published, Subpart G, Product Performance, and Subpart H, Label Development, are not expected to add significantly to economic impacts; however, when these subparts have been prepared, an analysis will be conducted and reported, if significant impacts are indicated.

An economic impact analysis of subpart B, D, E, and F of the guidelines was prepared in accordance with Executive Orders 11821 and 11949, OMB Circular No. A-107, and EPA Administrator's guidelines for conducting economic impact analyses on regulator proposals. This economic analysis was also prepared insofar as possible in accordance with Executive Order 12044 which was signed quite recently (March 23, 1978) and does not apply "in rulemaking proceedings pending at the time this order is issued, if an economic impact statement has already been prepared in accordance with Executive Orders 11821 and 11949." Although strict adherence to the provisions of Executive Order 12044 is not legally required for the proposed guidelines, the economic analysis did incorporate the spirit of those requirements where possible.

This analysis of economic impacts of proposed sections of the guidelines on data requirements for registering pesticides is not in as much detail as is anticipated for the analysis of guidelines finally adopted by the Administrator; this report reflects the best available data on economic impacts. Additional analysis is in the process and will be available by the time final guidelines are adopted. In addition, substantive comment is anticipated on economic impacts of the guidelines as proposed. The thrust of additional analysis will be in the direction of more detailed investigation with respect to the broad spectrum of groups impacted by the guidelines, directly and indirectly. These groups include basic presticide producers, pesticide formulators, pesticide users, and consumers.

Dated: August 28, 1978.

EDWIN L. JOHNSON.
Deputy Assistant Administrator for Pesticide Programs.

ECONOMIC IMPACT ANALYSIS OF GUIDELINES FOR REGISTERING PESTICIDES IN THE UNITED STATES

UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, AS AMENDED

SUBPART B: INTRODUCTION; SUBPART D: CHEMISTRY REQUIREMENTS; SUBPART E: HAZARD EVALUATION: WILDLIFE AND AQUATIC ORGANISMS; SUBPART F: HAZARD EVALUATION: HUMANS AND DOMESTIC ANIMALS

OFFICE OF PESTICIDE PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY

MAY 31, 1978.

I. INTRODUCTION

A. AUTHORITY FOR ECONOMIC IMPACT ANALYSIS

This report contains an analysis of the economic impacts that would occur if the Environmental Protection Agency (EPA) were to implement four proposed subparts of the guidelines for registering pesticides in the United States (guidelines) published under the authority of sections 3(c)(2), 8, and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. The subparts are Introduction, Subpart B; Chemistry Requirements, Subpart D; Hazard Evaluation: Wildlife and Aquatic Organisms, Subpart E; and Hazard Evaluation: Humans and Domestic Animals, Subpart F. These are the four subparts of the guidelines expected to generate significant economic impacts. Two other subparts to be published, Subpart G, Product Performance, and Subpart H, Label Development are not expected to add significantly to economic impacts. If they do, this analysis of economic impacts would be amended appropriately.

This economic impact analysis was prepared in accordance with Executive Orders 11821 and 11949, OMB Circular No. A-107, and the EPA Administrator's guidelines for conducting economic impact analyses (EIA's) on regulatory proposals. This analysis was also prepared in accordance with Executive Order 12044 insofar as possible under the circumstances. This order was signed by the President only recently (March 23, 1978) and does not apply "in rulemaking proceedings pending at the time this order is issued, if an economic impact statement has already been prepared in accordance with Executive Orders 11821 and 11949" (see Executive Order 12044, Section 3).

The major additional requirement in Executive Order 12044 is for an explicit analysis of regulatory alternatives. As indicated above, this is not legally required for this proposed rulemaking. Neither would it be necessary because

all stages of development and review of the guidelines have involved consideration of alternatives. Specifically, in drafting the guidelines, the Agency devoted a great deal of resources to evaluating alternative types of data and tests and alternative levels of requirements for each type. In making such evaluations, EPA has carefully considered the numerous comments received from experts outside the Agency, which often contained suggested alternative levels of requirements (see discussion below, p. 5).

Two major alternatives considered in the area of human hazard evaluation were (1) to require chronic and subchronic testing on inert ingredients in pesticide products as well as the pesticidal active ingredients, and (2) to require chronic and subchronic testing for formulated products as well as technical chemicals. The intent for both of these alternatives was to determine the effects of all ingredients in products. The first alternative would have doubled the testing required in this area and the second alternative would have increased the number of tests required by twenty-fold. Appendix E contains excerpts from the preamble to subpart F giving further details of the issues involved and the reasons why the alternatives were rejected. The preamble to subparts B, D, E, and F contain other examples of alternative approaches considered in preparation of the proposed guidelines. The Agency will continue to consider alternatives in its process of reviewing public comments on the proposed guidelines and on this economic analysis. Also, to develop a meaningful and explicit analysis of alternatives would require more time and resources than the Agency has available, and thus would be impractical in meeting the legislative mandate to issue guidelines.

B. BACKGROUND: PURPOSES OF THE REGISTRATION GUIDELINES

Under FIFRA, EPA is responsible for registering pesticide products, thereby permitting the registrant to market his product in commerce. The statute requires EPA to register a product only if its use does not cause "unreasonable adverse effects on the environment." In order to determine whether to register a pesticide, EPA generally requires the applicant to submit data on the potential effects of the pesticide on human health and environmental quality.

The statute specifically directs EPA to put its data requirements for registering pesticides in written form. FIFRA § 3(c)(2) states that: "The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of pesticide and shall revise such guidelines from time to time." Thus, to satisfy this statutory requirement, EPA has developed guidelines which state the conditions under which specific data woud be required to support the registration of a product, specify the standards for acceptable testing, provide references to test protocols in the scientific literature, and describe the format for reporting data.

In addition, based on its experience over recent years, EPA has found that written guidelines are necessary for an effective pesticide registration program. The 1972 amendments to FIFRA imposed a major task on EPA, the task of reregistering all currently registered pesticides. Under reregistration, the registrants of a currently registered product must supply or cite all data which would be required if it were a new product. Thus, to reregister products, EPA must be able to inform registrants of what data would be required. Without written guidelines, this is difficult to do and EPA encounters many problems on such matters.

The Agency has had difficulty in stating the specific data requirements which currently apply to registered products. Staff reviewers often have failed to provide requirements which were consistent for similar kinds of products. Reviewers also have failed to set standards for the satisfactory performance of new tests, including, for example, not identifying the substance to be tested. Reviewers also have failed to specify clearly how data from a test should be submitted. As a result, on occasion, registrants have had to repeat tests or supply data not originally called for. Similar problems have occurred in the registration of new products and have often caused lengthy delays in reaching registration decisions.

The problems with reviewing data submitted to the Agency were aggravated by absence of written guideline requirements. EPA has made several attempts to determine which data would not be required for reregistration, because valid data had already been submitted. Each attempt has failed because EPA found that it needed to conduct a more intensive review than originally believed necessary. It was not sufficient to determine only whether a set of test data had been submitted. Nor was it sufficent to review a registrant's summary of test results to determine whether apparent problems existed. The Agency has finally concluded that nothing less than an indepth review of each aspect of each test report, together with auditing of test laboratories, is necessary to determine whether any set of data is valid and satisfies reregistration requirements.

In view of its experience during recent years, EPA has concluded that specific, written guidelines are necessary to resolve these problems. In particular, the guidelines should significantly reduce the problems of consistency in establishing requirements and reviewing data.

These guidelines have been developed over the past 10 years. Initial drafting began in 1969, and the guidelines were initially proposed in the FEDERAL REGISTER in June 1975. Since then, drafts of the guidelines have been carefully and extensively reviewed by Agency staff and members of the public. EPA has held at least seven public meetings on the guidelines at which environmental, industry, academic, and Federal and State regulatory groups have participated. Each meeting has involved close review of each draft provision with particular consideration of the regulatory reasonableness of each requirement. The underlying question in each review has been: Is the cost of a particular requirement justified by the value of the data which EPA would receive? While there have been many comments and divergent opinions on the reasonableness of particular requirements, these proposed guidelines have received a highly affirmative endorsement from the scientific community. Industry, environmental, academic, and regulatory scientists generally agree that these proposed guidelines require the kinds of data which are minimally necessary to evaluate the safety of a pesticide. Moreover, there is a general agreement that the standards for acceptable testing are appropriate for generating the required data.

C. SCOPE OF ANALYSIS

The proposed guidelines for subparts B, D, E, and F would, to a considerable extent, merely state in one place and in formal fashion the data requirements which now are being imposed on firms wishing to register new pesticide products. However, some new data requirements are proposed in the guidelines. Identifying the cost of these proposed new requirements is a major purpose of this analysis. This analysis also provides estimates of the cost of satisfying existing data requirements.

Data submission may be required when a pesticide product is first registered, when a registration is amended (e.g., to add uses of the product), or when the product is reregistered. The 1972 FIFRA amendments require that all currently registered products be reregistered if they are to be marketed, and that applicants for reregistration supply or cite all data which would be required if it were a new product. Because many products were

registered before some current data requirements were imposed, many current product registrations are not supported by all the types of data which now would be required for a new product registration. Additionally, some previously submitted data were generated by methods which would be unacceptable today.

There are about 1,000 different active ingredients contained in presently registered pesticide products now being produced and marketed. The total number of active ingredients presently registered is about 1,460, of which about 460 are not in production. This analysis focuses upon the application of guidelines requirements to products containing the 1,000 active ingredients currently being produced. EPA assumes that the remaining 460 active ingredients will not be placed in production. (If they are not now economically viable, they are not likely to be viable in the foreseeable future.) The analysis also covers the cost of data required for registration of new products in the future. EPA assumes that approximately 15 new active ingredients will be introduced each year.

For both reregistration and new registrations, this analysis breaks these totals down into the cost of current data requirements and the incremental (added) cost of the new data requirements which would be imposed by the proposed guidelines. The incremental cost is defined as the difference between what is now required for new registrations (current practice costs) and guidelines requirements costs. The costs are translated into annual costs to producers and users of pesticides and to consumers in general. The magnitudes of annual costs (and projected economic impacts) are highly dependent on how soon the requirements are imposed.

The Agency plans to apply the data requirements in the final guidelines immediately to new registrations of new chemicals, but over a period of years to currently registered products. Once the final guidelines have been promulgated, most applications for new registrations will be required to satisfy all applicable provisions of the guidelines. (If a conditional registration program is approved in the legislation pending before Congress, some new products may be conditionally registered, even though they do not satisfy all data requirements.) EPA, however, would not expect all currently registered products to satisfy all of the guidelines data requirements as soon as the guidelines were finally adopted. The process of generating data for reregistration and making reregistration decisions simply cannot be done immediately. Because of the size of the task, EPA projects that it will require a period of more than 10 years to reregister the products containing the 1,000 active ingredients now in production. Currently registered products would become subject to the guidelines data requirements at different times during this period.

This analysis contains two scenarios which describe possible schedules for imposing the guidelines requirements on currently registered products. In both cases, the schedules are closely related to EPA's proposed program of establishing generic standards. Generally, a generic standard is a comprehensive discussion of the data available to the Agency on products containing a specific active ingredient and a delineation and explanation of the Agency's regulatory actions respecting those products. Both scenarios assume that each year EPA will establish 50 generic standards on currently registered products per year for a period of 10 years and beyond. Both scenarios also assume that the large-volume active ingredients used in agriculture and food production would be covered by generic standards before EPA establishes standards for the remaining active ingredients. Scenario No. 1 assumes that each standard would identify the schedule for submittal of missing data to obtain reregistration and that data gaps would be filled some years after the standard is established. Scenario No. 2 assumes that EPA establishes a program to identify data deficiencies for products before a generic standard is issued covering those products. EPA would then inform registrants of the missing data and require them to submit the data when the standard is published. This early notification program would expedite initiation of testing to determine potential hazard.

An analysis is presented of the benefits which the guidelines are expected to generate. Published guidelines are projected to have substantial benefits in connection with both reregistration and initial pesticide registration. It is of increasing importance to specify data requirements clearly to insure that human health and environmental risks are minimized while at the same time give registrants a "fixed target" for planning their R. & D. activities. Industry, agency staff, and the general public could all benefit from formal printed guidelines specifying data required for registrations. There are increasing concerns about the credibility of data necessitating not only guidelines for such data but also programs to check and insure the integrity of such data, which have been found wanting in some instances.

D. COST METHODOLOGY

To determine the incremental cost of the new data requirements in the guidelines, estimates were first made

of the number of times each test would be required and then of the cost per test, under both current practice and the proposed guidelines. Totals were computed by multiplication and the difference between them gave the incremental cost of the proposed guidelines.

EPA considered and rejected several methods of estimating the numbers of tests which would be required for reregistration. A complete review of all 34,000 registered products would provide the most reliable and precise estimates of the number of tests which would be required to complete reregistration. However, even with projected growth in resources, the Agency does not expect to complete this review task for 10 to 20 years or possibly longer. Consequently, this approach was not practical for purposes of this analysis. EPA considered another method, review of a sample of products and extrapolation from the results. This method was also dismissed, because, even a thorough review even of a small sample would be very resource intensive. A typical active ingredient appears in several products, each of which would have to be reviewed. Several person-months of effort would be required to adequately review the data for one product. In addition, the variability across pesticidal chemicals, due to chemical structures and use patterns indicate that the sample would have to be very large. Finally, EPA considered the use of outside experts as consultants or contractors to help in review of a sample. This method was also rejected since it would have required providing the consultants with data which are considered proprietary trade secrets. Futhermore, while this method would have reduced the number of Agency staff involved, it would still have required significant resources, as discussed above.

The approach selected for determining the number of tests which would be required was to use panels of experts from the Registration Division and the Criteria and Evaluation Division of the Office of Pesticide Programs. Panel members were selected because of their knowledge of the guidelines and their broad familiarity with pesticides and pesticides registrations. One panel was formed for each of the major areas: Environmental chemistry, product chemistry, fish and wildlife hazard, and human and domestic animal hazard. The product chemistry panel also provided the estimates for the special chemistry requirements on pesticide residues on tobacco.

These panels reviewed the sections of the proposed guidelines and estimated the number of times a particular test would be required. In addition, on the basis of their knowledge of pesticide registrations, they estimated the number of times a particular test would be required under current practice without the written proposed guidelines. Within two to four iterations, the individual panels reached consensus on the estimates. Finally, rough estimates were also obtained on data already in the Agency files which might satisfy the proposed guidelines requirements.

The estimated cost, both under current practice and under the proposed guidelines, of conducting each kind of test and submitting the data to the Agency was calculated using estimates from several sources. These sources included pesticide companies, private laboratories, governmental laboratories, and OPP personnel. (See appendix A for the sources of cost estimates for each test.) The cost estimates are based on a typical product. When more than one figure was available, an average cost was used. The cost of a particular test would vary, depending on the product tested. The reliability of the cost estimate varies with degree of standardization of the test. In addition, if one laboratory were commissioned to do a series of tests on a product or group of products, the cost per product of each test would likely be lower than the figures contained in this analysis. The costs of all tests were estimated using 1977 prices.

In order to estimate the cost of new registration and reregistration under current practice and under the standards proposed in these guidelines, it was necessary to make certain assumptions:

(1) That the number of applications for new registrations which will be submitted to the Agency annually can be projected from past experience.

(2) That applications for new products generally will be distributed into the same types of use patterns and chemical classes as currently registered products; accordingly the data requirements for new products would be imposed on new products with the same frequency as on currently registered products.

(3) That, if data are required to support more than one application for new registration or reregistration, in accordance with section 3(c)(1)(D) of FIFRA, the data will be submitted only once to the Agency and subsequently will be cited by the applicant or registrant; and that the costs of producing the data will be shared by all applicants and registrants required to submit or cite the data.

There are also some practical limitations to this analysis. Although the proposed guidelines attempt to state the data requirements for registration and the standards for acceptable testing, there may be variations from

these requirements. As is discussed in greater detail in the preamble to the guidelines, the proposed guidelines provide for waiver of data requirements and for deviation from the standards for acceptable testing. Moreover, additional data not specified in the guidelines may be required if the required data are not sufficient to evaluate the safety of the pesticide. All of these procedures would be administered on a case-by-case basis as the Agency reviews the data presently in its files and reviews applications for new registration and reregistration. No estimates were made of the impacts of these decisions.

In addition, no estimates were made of the economic impact of the proposed guidelines on amended registrations. A registration is amended if certain changes are proposed to its labeling or composition. Many amended registrations require none of the data which would be required by the subparts of the guidelines which are the subject of this analysis. Information is not available to estimate the number of amended registrations which would be affected by these proposed guidelines. Any impacts would be minor, however. Accordingly, the impacts on amended registrations are not included in this analysis.

This analysis includes estimates of the impacts expected under proposed § 163.40-5, "Retention and Submission of Raw Data, Specimens, and Samples of Test Substances." The cost of the data retention is included in the cost of performance of the kinds of tests described in subpart D, E, and F. Consequently, the impact of the data retention requirements are not separately estimated.

Congress is presently considering amendments to FIFRA which would change the procedures for registration and effect the economic impact of the proposed guidelines. If FIFRA is amended permitting use of generic standards, the 10-year reregistration scenarios are relevant and suggestive of economic impacts of the guidelines.

II. Summary of Findings

A major task faces EPA and the pesticide industry, to reregister existing pesticides under FIFRA. The 1972 amendments to FIFRA require that currently registered products be reregistered, if they are to continue to be marketed as pesticides. This task is far behind schedule; even though it was to have been completed by 1976, little progress has been made to date. EPA is now proposing to publish formal guidelines to make the process of reregistering pesticides and registering new pesticides more efficient. Under FIFRA § 3(c)(2), the Agency is required to publish such guidelines for registration data requirements and to update them from time to time. Guideline requirements must be the same for existing pesticides and new ones.

Four subparts of the guidelines have been drafted and are being proposed to facilitate programs to reregister pesticide products (if submitted for reregistration) and to register new pesticide products. These subparts (B, D, E, and F concerned with introduction, chemistry, wildlife hazards and human hazards respectively) contain the requirements which are expected to have the most significant economic impacts.

These proposed subparts of the guidelines are projected to generate significant benefits to the pesticide regulatory program in the United States. They would also have economic impacts of varying significance on pesticide producers, formulators, and users. This analysis focuses on economic impacts during the decade of the 1980's. This is the period during which the major portions of data requirements for these four subparts of the guidelines would be satisfied.

The principal findings of the analysis are:

1. A distinct need exists for printed guidelines on data requirements for registration of pesticides. The complexities and importance of data requirements for registration of new pesticides indicate that it would be useful to have formal printed guidance available for use by registrants, agency staff, and the general public. Also, printed guidelines are needed to facilitate determining whether currently registered pesticide products now in use are adequately tested by today's scientific standards so that they may be reregistered. Most products now registered do not appear to have sufficient data on file to support reregistration under current practice requirements (or the proposed guidelines). In some cases, existing data appear to be completely unreliable or invalid. As indicated below, substantial benefits to the Agency, industry and the public can be obtained by use of printed guidelines in pesticide registration programs.

2. The data requirements specified in the guidelines would reduce human health and environmental risks from pesticide use through better data for decision making on pesticide registrations. With more complete and reliable data, pesticides which present unreasonable risks would be more easily identified so that they would not be registered. In the process, health and environmental risks of pesticides would be reduced, while allowing benefits to be obtained from use of those pesticides which do not present such risks. Indications are that exposure to toxic chemicals such as pesticides is

taking a heavy toll in terms of human health losses and costs of treatment. Reduced risks are indicated particularly with respect to the guidelines because of increased data requirements on product chemistry and human hazards. The guidelines subpart on product chemistry would lead to reduced risks of exposure to highly dangerous and toxic contaminants or impurities in pesticides. The human hazard subpart would improve registration decisionmaking by providing critical acute, subchronic, and chronic toxicology data.

3. Issuance of the guidelines would produce significant benefits for EPA's registration process. Better specification of data requirements, together with specification of test standards and uniform data reporting formats, would make the process more efficient. Program costs would be lowered and reviews would be expedited thus producing decisions more quickly.

4. Printed guidelines would benefit the pesticide industry in several ways. Applicants for registration or reregistration would need to make fewer submissions to obtain EPA decisions. Presently, an average of 3.4 submissions are required per registration. This could be reduced significantly by the guidelines. In the process, the applicant could get his product on the market sooner, in competition with other firms. Better specification of the data requirements to support a pesticide registration would lead to better scheduling of data development activities, both for new pesticides and for currently registered products. This reduces risk of the nonregisterability of candidate pesticides as firms have a better base for decisionmaking, as does EPA. Fewer pesticide industry resources would be wasted on the development of "losers". Reduced risk of investing in such "losers" would bring forth additional incentives to invest in the development of more effective and environmentally acceptable pesticides.

5. The guidelines would increase the cost of data for registration of an average active ingredient as follows:

[Dollars in thousands]

Subpart	Current practice	Guidelines	Incremental	Percent change
Product chemistry	$57	$67	$10	18
Environment and special chemistry	132	132	0	0
Fish and wildlife hazard	9	12	3	33
Human and domestic animal hazard	90	169	79	88
Total	289	381	92	32

The major incremental cost is in the area of human health/domestic animal hazard data, where the increase is nearly 90 percent. The overall increase for the four subparts is about one-third (32 percent).

6. Data requirements for large volume active ingredients with potential for high exposure to humans and environmental systems are much greater than for the average active ingredient. For a large volume active ingredient, data costs for the four subparts of the proposed guidelines would be increased as follows:

[Dollars in thousands]

Subpart	Current practice	Guidelines	Incremental	Percent change
Product chemistry	$57	$67	$10	18
Environment and special chemistry	225	225	0	0
Fish and wildlife hazard	50	75	25	50
Human and domestic animal hazard	350	600	250	71
Total	682	967	285	41

The percentage increase in incremental costs for such major active ingredients of 41 percent is greater than for the average active ingredient (32 percent, as noted in item 5 above).

7. The guidelines would increase the cost of data for registration of an average formulation of a pesticide as follows:

Subpart	Current practice	Guidelines	Incremental	Percent change
Product chemistry	$2,950	$5,200	$2,250	77
Environment and special chemistry	1,712	1,712		0
Fish and wildlife hazard	520	703	183	36
Human and domestic hazard	3,041	4,317	1,276	42
Total	8,223	11,932	3,709	46

These costs vary greatly among formulations. For most (90 percent of formulations), the guidelines cost would be $8,900, compared with $5,100 for current practice (increment of $3,800). These costs reflect the level of data most often required of the formulator. However, for some formulations (0.5-1.0 percent), the costs of meeting the guidelines requirements are much higher, e.g., $200,000 of which about 90 percent is required under current practice. Incremental costs of the guidelines would generally be nominal in such cases. The data costs for such formulations would normally be incurred by the basic manufacturers of the active ingredient, or would be substantially shared with (or among) formulators.

8. The incremental costs of the proposed four subparts of the guidelines would be $12 million per year for 15 new active ingredients and their formulations, which have projected to be registered per year in the future. This cost would be in addition to a base of $27 million under current practice, bringing total costs of compliance for new registrations to $39 million per year.

9. For reregistration of an existing product under the guidelines, the registrant would be required not only to meet the incremental requirements of the guidelines over current practice, but also to fill any data gaps to meet current practice requirements. The data gaps would be substantial for most registered products. For the average active ingredient, and all of its formulations, the data gap costs and other costs are as follows:

	Now in production		Not now in production	
	Dollars	Percent	Dollars	Percent
Current practice:				
Acceptable, data on file	125	15	54	22
Data gap	474	57	146	58
Subtotal	599	72	200	80
Guidelines	834	100	250	100
Incremental	235	28	50	20
Number of active ingredients	1,000		460	

This table demonstrates that the costs of meeting current practice requirements (those now required for new active ingredients) are a far more important factor in reregistration of existing products than are the incremental costs of the guidelines.

10. Economic impacts of the guidelines were estimated assuming that imposition of data requirements would be coordinated with the new generic standards registration program. Annual costs were projected for the period 1980-89 for meeting the incremental requirements of the guidelines and for meeting current practice requirements (including those not met already, i.e., "data gaps"). Two scenarios were projected, each assuming generic standards are applied to 50 existing active ingredients and 15 new chemicals (including their formulations) per year. The scenarios further assume:

Scenario No. 1—Data gaps would not be identified and filled until after a standard covering the product had been issued.

Scenario No. 2—Registrants of 100 chemicals per year are given early notification of data deficiencies in existing registrations and are required to submit satisfactory data at the time the standard is being developed.

Scenario No. 2 is representative of many other possible reregistration scenarios involving an early notification program. Over the period 1980-89, the annual costs would vary depending on the specific notification schedule, but the overall costs would be comparable over the decade.

11. The number of reregistered active ingredients scheduled to be brought under guidelines requirements during the first 10 years of implementation by issuance of generic standards would be 500 for scenario No. 1 and 750 for scenario No. 2. These active ingredients account for most of the active ingredient volume used.

12. Under scenario No. 1, products of 395 active ingredients would probably be reregistered during the 1980's, while those of 105 other active ingredients scheduled for reregistration probably would not. Projected actual outlays to meet guidelines requirements for reregistration for those products are $322 million ($222 million data gap and $100 million incremental costs).

13. Under scenario No. 2, products of 525 active ingredients probably would be reregistered during the 1980's while those of 225 other active ingredients scheduled for reregistration probably would not. Projected actual outlays to meet guidelines requirements for registration of these products are $376 million ($262 million data gap and $114 million incremental costs).

14. The number of active ingredients in production under EPA registrations

would be about the same at the end of the 1980's as now (about 1,000). Though 105 to 225 active ingredients now in production probably would not be reregistered, there would be about 150 new ones added, if historical trends continue. By the end of the 1980's, there would still be a relatively large number of active ingredients now in production (250 to 500) which had not undergone reregistration. About one-half of these chemicals probably would not be submitted for reregistration under generic standards to be issued during the 1990's.

15. Under each of the scenarios, the 460 registered active ingredients not in production during recent years are not projected to be submitted for reregistration. In general, generic standards for these would not be planned during the 1980's, if at all. The economic impact of the guidelines and/or filling data gaps on these active ingredients is of limited economic significance for the foreseeable future.

16. Projected annual costs of the two scenarios for reregistration and new registrations are in the following ranges during the 1980's:

[In millions of dollars]

	Current practice *	Incremental	Total
Scenario No. 1 (50 standards per year for old chemicals plus 15 new)	$36-$60	$15-$29	$53-$89
Scenario No. 2 (scenario No. 1 plus 100 notices for old chemicals per year)	33- 80	14- 38	47-118

* Including data gaps.

The annual costs peak out for both scenarios in 1983 and decline through the remainder of the 1980's. The annual costs peak out at higher levels for scenario No. 2 due to the early notification program, and accordingly are lower than scenario No. 1 by the end of the decade.

17. Under the two scenarios, the costs of the guidelines would add slightly to the sales value of pesticides at the basic producer level. The increases would be as follows:

[In percent]

	Current practice*	Incremental	Total
Scenario No. 1 (50 standards per year for old chemicals plus 15 new)	1.3-2.2	0.4-1.1	1.7-3.3
Scenario No. 2 (scenario No. 1 plus 100 notices for old chemicals	1.0-3.0	0.4-1.4	1.4-4.4

*Including data gaps.

18. Costs of implementing the guidelines would result in significant increases in projected total basic pesticide R. & D. expenditures, as follows:

[In percent]

	Current practice*	Incremental	Total
Scenario No. (50 standards per year for old chemicals plus 15 new)	17.8-32.1	6.3-15.5	24.1-47.6
Scenario No. 2 (scenario No. 1 plus 100 notices for old chemicals)	13.9-42.8	5.9-20.3	19.8-63.1

*Including data gaps.

Basic R. & D. is generally conducted by the large manufacturers of active ingredients (and large formulators) and includes all such costs, of which only about one-third are registration related (see item 19).

19. Costs of implementing the guidelines would amount to a very large increase in projected basic registration-related pesticide R. & D. as follows:

[In percent]

	Current practice*	Incremental	Total
Scenario No. 1 (50 standards per year for old chemicals plus 15 new)	61.7-111.1	22.1-53.7	83.8-164.8
Scenario No. 2 (scenario No. 1 plus 100 notices for old chemicals)	48.5-148.1	20.6-70.4	69:1-218.5

* Including data gaps.

These costs would be borne largely by the larger firms, e.g., basic manufacturers, but would be borne by others as well, more than at the present time. This point is discussed further below (see item 27).

20. Costs of implementing the guidelines, if passed directly to users of pesticides, would add slightly to such projected expenditures during the 1980's as follows:

[In percent]

	Current practice *	Incremental	Total
Scenario No. 1 (50 standards per year for old chemicals plus 15 new)	0.6-1.1	0.2-0.5	0.8-1.6
Scenario No. 2 (scenario No. 1 plus 100 notices for old chemicals)	0.5-1.4	0.2-0.7	0.7-2.1

* Including data gaps.

21. Projected actual outlays to reregister products containing currently registered active ingredients (under the guidelines) are $473 million over the 1980's and early 1990's. This is about one-half of the estimated total data cost if all products containing all 1,460 active ingredients were reregistered under the guidelines ($949 million). The breakdown of this total cost figure is as follows:

[In millions]

	Scenario No. 1	Scenario No. 2
Reregistration during 1980's	$322	$376
Reregistration later	151	97
Total reregistration	473	473
Acceptable data on file	150	150
Data for products not reregistered	326	326
Total	949	949

In other words, about one-half of the total would not be incurred because of data already on file and products not submitted for reregistration.

22. Producers and users of major active ingredients would be affected quite nominally by implementation of the guidelines. These major active ingredients, which number about 200 out of the 1,000 in production, account for up to 90 percent of total active ingredient volume.

23. Implementation of the proposed guidelines requirements with respect to the remaining 800 active ingredients with smaller volume current production is of more potential significance. Of the 800 smaller volume active ingredients now in production, 300 to 550 would come under guideline/generic standards during the 1980's of which 105 to 225 would become uneconomical unless specific waivers or other similar actions are taken. (Provisions in legislation pending before Congress direct the Administrator to consider the potential cost impacts on industry incentives to incur the costs when establishing registration data requirements for minor use pesticides.) The number expected to be withdrawn is only slightly greater if the guidelines are implemented as compared to implementation of current practice requirements (25 to 35 active ingredients depending on the scenario). When reregistration of existing active ingredients is completed, products containing about 645 active ingredients are projected to be eventually reregistered. These 645 active ingredients comprise an estimated 95 percent of the volume of pesticides currently produced.

24. Under scenario No. 1, agricultural pesticide user expenditures would be increased proportionately somewhat more than other sectors. This is due to the emphasis on reregistration of large volume and agricultural pesticides in that scenario. The early notification aspect of scenario No. 2 tends to equalize the impacts among the sectors. The percentage increases in pesticide user expenditures during the 1980's are as follows:

[In percent]

Sector	Scenario No. 1	Scenario No. 2
Agriculture	1.4	1.3
Indiyidual, community, government	0.7	1.0
Home/garden	1.0	1.4
All users	1.2	1.3

25. Currently there is a significant problem on the registration of pesticides for many minor uses (small volume uses) in agriculture and elsewhere in the economy. Manufacturers often cannot justify incurring the data costs for registering products for such uses, whether they are formulated from large or small volume active ingredients. Indications are that the "minor use problem" would not be added to greatly during the foreseeable future due to the incremental costs of the guidelines. Provisions for directing EPA to consider the cost impacts of data requirements for minor use registrations are included in amendments to FIFRA pending before Congress. Many of the small volume active ingredients, from which some minor use products are formulated, would not be brought under generic standards for several years, thus allowing time for data to be generated or alternatives found. Minor use problems can be minimized by programs presently available, for example, the IR-4 program.

26. Basic R. & D. and production of pesticides is quite oligopolistic (highly concentrated). The oligopoly core of major firms in most cases can readily accommodate the increased requirements of the proposed guidelines. The major impact of the guidelines on competition in the industry is to add barriers to future potential competitors and to make it more difficult for smaller firms to compete effectively.

27. Formulators, who have traditionally not directly incurred much of the registration data costs, would incur more of such R. & D. costs under the guidelines. Large-scale formulators would be able to accommodate such costs quite readily by sharing them with basic manufacturers to a considerable extent. However, small volume formulators, many of whom are not now operating on a large-scale commercial basis, might choose not to formulate some of their products. In instances where small volume active ingredients are no longer available for formulation into products, firms may choose to shift to formulations with other active ingredients. Short-term adjustment problems would be caused in such instances. Pending amendments to FIFRA would alleviate some of the impacts of the proposed guidelines on formulators who purchase registered manufacturing-use products. Inadequate data presently exist to fully evaluate impacts upon smaller firms in the long term. This is under further analysis by EPA, with contractor support to be added in the near future.

28. Overall consumer costs of the guidelines (direct and indirect) would be minimal ($0.10 to $0.35 per capita on an annual basis during the 1980's for incremental and total costs respectively.)

29. No significant employment, output, inflation, or other macroeconomic impacts are projected from implementing the guidelines, e.g., $50-125 million per year, equal to 0.004-0.01 percent of current GNP. Significant impacts are limited to the sector level and parts of the pesticide industry.

30. In the pesticide industry, some employment dislocation could occur (total of 38-75 jobs per year; 8-15 jobs per year due to incremental requirements). The significance of these job dislocations is expected to be minimized due to projected growth in output in the industry.

31. No significant energy impacts are projected from implementing the guidelines.

32. There could be constraints on implementation of the guidelines during the early 1980's due to shortages of expertise and facilities for certain R. & D. areas, e.g., toxicology due to increasing testing requirements under FIFRA and other statutes. The Agency is exploring this matter in detail to determine its full significance to the overall chemical industry, of which pesticides are a small but important part.

33. The Administrator of EPA is mandated by FIFRA to revise the published guidelines from time to time as appropriate. Such revisions would be made when a data requirement is found to not be cost effective, e.g., it does not add sufficient information to justify costs and/or impacts on registrants and users of pesticides.

III. Benefits of the Guidelines

The proposed guidelines, if implemented, would generate benefits as well as costs. The purposes of this section are to identify the benefits and to provide a qualitative analysis of these benefits to pesticide producers, users, and the general public. Following the benefit analysis, the remainder of this report concerns costs and economic impacts of the guidelines, against which the benefits must be weighed.

The analysis of benefits covers direct benefits which would be generated by improving the pesticides regulatory function as it impacts upon registration applicants in industry and elsewhere. It also concerns indirect benefits generated as a result of a more efficient registration program, which impact upon pesticide users, consumers, and the general public.

A. Direct Benefits

The direct benefits of the guidelines to industry can be put into two classes—those derived from reducing uncertainty of the pesticide producer as to the data requirements for registering a pesticide, and those derived from reducing the time required to register a pesticide.

1. *Reduced uncertainty of registerability of pesticides.* Investments must be viewed with respect to expected level of returns and the risk associated with the expected return. Pesticide producing companies search for investment opportunities which have not only a high expected return but a low variance, i.e., low risk. The lower the variance about the expected average of returns, the more desirable is the venture; uncertainty, or the threat of uncertainty, retards investment funding.

The guidelines would have a direct and perceptible impact upon reducing the uncertainty surrounding a given research and development (R. & D.) venture as perceived by pesticide producers. They have expressed the view that EPA, in the past, inconsistently applied data requirements for pesticides. They have also charged that delays attributable to EPA's requests for additional data to support registration not only have absorbed early profits which would have been obtained if the product had been on the market, but that these delays have added to the uncertainty which surrounds the registration process with unwritten guidelines (EPA, 1975).

2. *Reduced time to obtain registrations.* The guidelines minimize problems related to registration uncertainty by specifying the data requirements a candidate pesticide must meet in order to be registered. Once the proposed registration guidelines have become familiar to users of these guidelines, there would be two immediate benefits: The review time within EPA to process a registration would decline and, as a result, the pesticide would be able to enter the market at an earlier date. In fact, the drafting of the guidelines and their informal use during recent years may have already contributed to reduced EPA review time on pesticide applications. In 1976, the elapsed time from discovery to registration for newly registered products declined sharply (from 93 months in 1975 to 74 months) (NACA, 1976).

It is of critical importance to registrants of new chemicals to place the new products on the market ahead of upcoming products competing for the same market. The first product to be placed effectively on the market for a given use has a good chance of main-

taining a permanent advantage over later arrivals. The reasons relate to market establishment (set up of distribution channels and contacts; advertising and promotion; user allegiance, etc.) and to economies of scale in production. The first large scale plant is likely to enjoy cost advantages for an extended period which other firms cannot overcome because of the larger established production of the first firm to obtain registration. The benefit in this case is a long run phenomenon whereby firms are more encouraged to invest to "beat the competition to market", and in the process expand industry R. & D. of pesticides in competition for the consumer's dollar.

3. *Lower R. & D. costs.* Producers of pesticides would tend to benefit from the guidelines because, after the guidelines take effect, fewer R. & D. resources would be wasted on "losers". Fewer resources would be misspent on the development of products thought to be registerable but upon further closer preregistration testing are screened out. The guidelines would effect a reduction in these cases and, as a result, eliminate the dead weight burden of R. & D. expense which is undertaken simultaneously with registration and which, via a more thorough screening process, can be eliminated. The expenses which would be eliminated include those related to establishment of a production process and a pilot plant. Eliminating these costs alone can result in savings from two to three million dollars per product via early detection of unregisterable pesticides.

Better use of scarce laboratory facilities and expertise is possible due to the publication of the guidelines, since data requirements are more explicit, thus facilitating large scale operations, advance planning, and efficient scheduling. This could be quite significant during reregistration of existing pesticides, which could stretch capacity to the limit. Such a situation could occur due to increased demand for such work on chemicals to meet requirements under various Federal statutes.

4. *Reduce costs of registration review.* The guidelines would reduce EPA pesticide program costs as less time and resources would be needed to process applications for registration. Fewer applications would need to be returned to applicants for resubmission with additional data. During fiscal year 1977, the average number of submissions is 3.4 per application granted. The guidelines are expected to reduce this number substantially.

B. INDIRECT BENEFITS

Presented below are some of the indirect longer term benefits which can be attributed to the issuance of the guidelines.

1. *Fewer RPAR's and hearings.* One long term benefit to industry, EPA, users, and the economy in general is a reduction in the probability Agency issuance of rebuttable presumptions against registration (RPAR's) and cancellations/suspensions. Pesticide R. & D. based on today's standards for registration may not be relevant in the future, and products which have been registered may have RPAR's issued against them in the future. The improved data called for in the guidelines, compared to current practice, and the improved perception of registration requirements by industry, Agency staff, and the general public, would reduce the chances of products being registered and marketed for a time, only to end up being RPAR'd or canceled/suspended.

2. *Lower long term prices of pesticides due to shift in supply curve.* As a result of reduced uncertainty, lower costs, and other efficiencies noted above from the guidelines, the long run supply curve for pesticides would shift toward the right (increasing supply), apart from cost effects of the guidelines which shift the supply curve in the opposite direction. Therefore, since there is no a priori reason to expect the guidelines to cause a shift in demand, there would be a tendency for the equilibrium price of pesticides to decline, apart from the cost impacts of the guidelines which are discussed later in this report. This supply effect means that the supply price for a given quantity of pesticides would be less, due to such benefits of the guidelines, than would be the case without them.

3. *Reduced costs due to reduced health and environmental risks of pesticides.* The guidelines, due to information they would require to be submitted and the efficiencies involved in making risk/benefit decisions on pesticide registration applications, would reduce risks of health and environmental impact in a cost effective fashion, to the benefit of current and future generations. Indications are that human health costs due to chemical pollution at this time are still mounting with increasing cancer rates, especially in areas heavily impacted with chemical pollution (CEQ, 1977).

One of the findings that the Administrator is required to make in order to register a pesticide, is that the pesticide will not generally cause unreasonable adverse effects on the environment when used with widespread and commonly recognized practice. The data to be obtained under the proposed guidelines is to provide a better basis for scientific determination of the likely effects on man and the environment of pesticides for which registrations are sought. Registration applicants submit data identifying the components of their products, both intentional and unintentional, the fate of these components in the environment under likely use conditions, and the potential hazard to man, wildlife, and the environment associated with the product. In effect, the costs of data under the proposed guidelines buy data to improve determination of potential risks. The increased data requirements in the guidelines and the specificity obtained by printed guidelines combine to reduce the potential for future human and environmental risks when used in EPA registration programs.

Benefits of the intended use of the data requirements can be shown by examples. First, there are registered pesticides which are now known to contain impurities thought to be potential carcinogens. Within the last 2 years, much study has been done on a group of impurities called nitrosamines which have been found in registered pesticide products and are possible carcinogens. The proposed guidelines in the area of product chemistry, including "Discussion of Unintentional Ingredients" and "Product Analytical Methods," are designed to identify impurities such as the nitrosamines. The type and level of impurities identified would be used to assess the risks of acute or chronic toxicity to man or the environment.

Second, additional emphasis is being placed on the long term or chronic exposure effects of pesticides. The closely related pesticides aldrin and dieldrin were registered and used for several years before they were found to be carcinogens in test animals. These two pesticides have since been cancelled by EPA. The data from tests under the proposed guidelines including "Chronic Feeding" and "Oncogenicity" would be expected to better identify potential or actual carcinogens.

Subpart D, Chemistry contains two broad areas of requirements, one covering product chemistry and the other covering environmental chemistry. In addition, Subpart D contains several sections devoted to special chemistry data requirements; this latter area primarily concerns data on pesticide residues in tobacco.

The product chemistry guidelines would require data on the composition of a pesticide product and a commitment from registrants that the composition of the product, when manufactured and distributed, would not vary from the composition evaluated at the time of the registration application. The product chemistry guidelines would require a significant amount of supporting information which would explain how the registrant prepared his statement of composition.

The environmental chemistry guidelines in subpart D would require data on the fate of a pesticide product once it enters the environment. These data requirements generally woud apply to pesticides intended for "outdoor application" as that term is defined in 40 CFR § 162.3(cc) of the registration regulations. The term includes any pesticide application that occurs outside or whose consequences would be used to define what chemical substances remain in the environment after a pesticide is used, how long and at what levels the residues persist in the environment, and where the residues are likely to be found in relation to where the product has been used.

The environmental studies, from which data would be required, are divided generally into physical and chemical degradation, metabolism, mobility, field dissipation, and accumulation. Physico-chemical degradation studies identify residues which are formed through the action of water or sunlight on a product and determine the fate of those residues. Metabolism studies identify pesticide residues formed when the product is placed in water, activated sludge, or various kinds of soil. Mobility studies predict the movement of a pesticide and its residues outside the treated area, through leaching, volatility, adsorption, or dispersal by water. Field dissipation studies are conducted under actual use conditions at several sites to confirm data generated by required laboratory studies. Accumulation studies measure the propensity of a pesticide or its residues to collect in rotational crops, fish, and irrigated crops.

These environmental chemistry data would be collected and evaluated together with toxicity data to assess the potential hazards to man, fish, wildlife, or other nontarget organisms resulting from use of a pesticide. These data would indicate the levels of a pesticide and its residues to which man or other nontarget organisms might be exposed. Toxicity data would then be used to determine the nature of the risk created by exposure to those levels. The environmental chemistry data would also indicate whether the environmental behavior of a pesticide or its residues could lead to loss of land and water resources or could adversely affect important microbial populations.

Subpart E contains requirements for data on the toxicity of pesticides to various wildlife and aquatic organisms. EPA would use these data to evaluate the effects on nontarget species which potentially could result from use of a pesticide product. EPA has chosen to require testing of a few species which are representative of the vast number of species likely to be exposed to a pesticide. Subpart E also includes a wide variety of tests which are designed to evaluate the diverse ways in which a pesticide could affect fish or wildlife species. Virtually all pesticides would be tested for short term toxic effects resulting from high levels of exposure. Many others would be examined for their effects on a species' reproduction. Finally, some chemicals would be studied under actual use conditions in the field, and all indications of toxicity would be carefully evaluated.

Subpart F contains tests designed to predict the harmful, or toxic, effects which pesticides might have on humans. The guidelines contain a series of data requirements based on animal testing which would evaluate a number of different toxic effects including: acute lethality by various routes of exposure; skin and eye irritation; nervous system effects; general toxicity from subchronic and lifetime exposure; oncogenic, teratogenic, mutagenic, and reproductive effects.

Appendix D contains a more detailed discussion of the benefits to be obtained or use of the data that the test results on data submissions under the proposed guidelines will provide.

IV. Incremental Cost of the Guidelines

The purpose of this section of the report is to provide basic cost data for the economic impact analysis reported in later sections of the report. Specifically, this section includes: (1) Unit cost estimate for each test/data requirement under current practice, guidelines and difference, i.e., incremental cost; (2) the number of times that such unit costs would be incurred and aggregate costs if all products now with registrations were reregistered, which is not expected to be the case (33,750 registrations involving 1,460 active ingredients are now on file); (3) the number of times that unit costs would be incurred and aggregate costs per year for new registrations (2,800 registrations, involving 15 new active ingredients, assuming one manufacturing-use product per new active ingredient.[1]

A. Product Chemistry

Table 1 provides a compilation of the number and cost of tests or data submissions which would be required by the product chemistry guidelines, and under current practice, for comparison. The incremental costs for all tests or submissions are calculated to be $89.9 million. Under the product chemistry guidelines, the Agency would receive a precise statement of the composition of the product, including active ingredients, intentionally added inerts, and impurities. The type of data required in the proposed guidelines for product chemistry is not greatly different from current practice. New areas for which data are now required that would reflect increased costs include a theoretical discussion of the components which either occur or might occur in a product, and a certification of the limits of the proportions for which the components in the product will likely be found. The requirement that the results of a sample analysis be submitted has been increased by requiring that five separate samples be analyzed as compared to one in current practice. This extension, along with the new items, account for approximately $50 million of the $90 million incremental costs. A more detailed description of the manufacturing process for formulations adds $23 million because of the large number of products involved.

Table 2 provides estimates of the costs of providing data on product chemistry under current practice and the guidelines for an average new active ingredient. The cost per active ingredient is $10,013 higher under the guidelines than under current practice. This represents a 17.5 percent increase in cost over current practice. Therefore, under the assumption that products containing 15 new active ingredients will be registered each year, the increase in total cost would be $150,195 per year for the requirements associated with the active ingredients.

Table 3 provides estimates of the costs of providing product chemistry data for a new formulation under current practice and the guidelines. These data are in addition to data required for the active ingredient. The incremental cost of the product chemistry data requirements of the proposed guidelines for a new formulated product would be $2,250 in comparision to current practice. This increases the cost for product chemistry by 75 percent current practice. Assuming these data requirements are imposed on the expected 2,800 new formulations per year, a cost increase of $6.3 million each year would result, in addition to costs of meeting the requirements associated with the active ingredient.

Appendix D contains a tabular presentation of the Agency's rationale for changing the data requirements for those of current practice to those in the proposed guidelines.

B. Environmental Chemistry

The environmental chemistry guidelines describe test requirements which would generate data on the fate of pesticide in the environment. The proposed guidelines for environmental

[1] From 1967 to 1975, the number of new registrations containing new active ingredients averaged 15 per year (range of 5 to 20, with no strong trend). In the past 4 years, the Agency has issued 11,140 new registrations, or about 2,800 per year.

chemistry reflect the current requirements in that area. Therefore, as shown in table 4, there are no incremental costs attributable to the proposed guidelines as compared to current practice. The products affected and the cost of performing a particular test are the same under current practice and the guidelines for environmental chemistry.

Under the asumption that the percentage of new active ingredients and new formulated products requiring a particular test would be the same as for currently registered ingredients and products, tables 5 and 6 compute the cost of the environmental chemistry requirements for new active ingredients and new formulated products, respectively. Again, there are no incremental costs attributable to the proposed guidelines.

Appendix D contains a tabular presentation of the Agency's rationale for changing the data requirements from those for current practice to those in the proposed guidelines.

C. SPECIAL CHEMISTRY REQUIREMENTS

Tolerance Clearance—A pesticide whose use may result in residues in food or feed is required to have a tolerance or an exemption from a tolerance. This requirement is established in the Federal, Food, Drug, and Cosmetic Act. There would be no economic impacts attributable to the guidelines as a result of this requirement. The guidelines merely note that residue data may be required to support the application for a new use of pesticide.

Pesticides on Tobacco—Tobacco, unlike food or feed crops, does not require a tolerance or exemption from tolerance. Data requirements have been developed to determine human exposure to pesticide residues which may result from the pesticide use on tobacco. The special chemistry guidelines codify these requirements. Table 7 provides estimates of the number and cost of tests to be required during reregistration by the guidelines. Since the guidelines reflect the Agency's current practice in this area, the number and cost of tests are the same under both current practice and the guidelines. As can be seen in the table, there would be no incremental costs attributable to the guidelines as compared to current practice.

Given the assumption that new products will be similar to currently registered products, table 8 shows the percentage of active ingredients requiring data under these special chemistry guidelines. The cost of data for an average new active ingredient is computed for both current practice and the guidelines. Again, there would be no incremental costs attributable to the guidelines as compared to current practice.

Appendix D contains a tabular presentation of the Agency's rationale for changing the data requirements from those for current practice to those in the proposed guidelines.

D. FISH AND WILDLIFE HAZARD

The guidelines subpart E Hazard Evaluation: Wildlife and Aquatic Organisms describes test requirements which would generate data to evaluate the hazards that pesticides may pose to birds, wildlife, fish, and other aquatic organisms. The standards for conducting the required tests described in the guidelines are similar to the standards used under current practice. The guidelines would, however, require certain data more frequently than under current practice. Table 9 provides estimates for the number and costs of the tests required for reregistration under current practice and the guidelines. For reregistration the incremental costs attributable to the guidelines would be $11.4 million for the fish and wildlife hazard requirements, given the assumptions of this report.

Table 10 provides estimates of the percentage of new active ingredients which would require the tests as described in the guidelines. For comparison, estimates are provided under current practice also. For a new active ingredient it would, on the average, cost $3,449 more to submit the fish and wildlife data required under the guidelines than under current practice. Under the assumption that 15 new manufacturing-use products would be registered each year, the incremental annual cost for new active ingredients under the proposed guidelines would be $51.7 thousand.

Table 1

Number and Cost of Tests/Submissions for Product Chemistry:
Comparison of Current Practice with Proposed Guidelines
Applied to Reregistration

Proposed Guidelines Requirement	Material[1]	Number Tests/Submissions		Cost Per Test/Submission		Totals		Difference
		Current Practice	Guidelines	Current Practice (Dollars)	Guidelines (Dollars)	Current Practice ($000's)	Guidelines ($000's)	($000's)
Description of Manufacturing Process	MUP	1,610	1,610 + 800[2]	250	1,000 + 100[2]	403	1,690	1,287
Description of Manufacturing Process	Form	31,195	31,195	250	1,000	7,799	31,195	23,396
Discussion of Unintentional Ingredients	MUP	0	1,610 + 800[2]	0	100 + 25[2]	0	181	181
Discussion of Unintentional Ingredients	Form	0	31,195	0	100	0	3,120	3,120
Product Analytical Methods	MUP	1,610	1,610 + 800[2]	55,000	60,000 + 2,000[2]	88,550	98,200	9,650
Product Analytical Methods	Form	2,700	2,700	10,000	10,000	27,000	27,000	0
Product Analytical Methods Formulated Products Produced by Integrated System	Form	100	100	55,000	60,000	5,500	6,000	500
Product Analytical Data	MUP	1,610	1,610 + 800[2]	300	1,600 + 1,600[2]	483	3,856	3,373
Product Analytical Data	Form	31,195	31,195	300	1,600	9,359	49,912	40,553
Declaration/Certif. of Limits	MUP	0	1,610	0	100[3]	0	161	161
Declaration/Certif. of Limits	Form	31,195	31,195	0	100[3]	0	3,120	3,120
Physical/Chemical Properties	MUP	1,610	1,610 + 800[2]	1,500	1,600 + 1,600[2]	2,415	3,856	1,441
Physical/Chemical Properties	Form	31,195	31,195	1,500	1,600	46,793	49,793	3,119
						188,302	278,203	89,901

1/ MUP - manufacturing-use-product
Form - formulated product

2/ For product chemistry it is assumed that there will be 1,610 materials for which data will be needed. This number includes the 1,463 active ingredients plus an additional 10% added to account for those materials which may have more than one distinctive form of the manufacturing-use products which are technical grade. It is further assumed that there are 800 registrations (containing one or more of the 1,610 materials) which are modified technicals or concentrates. These products would require additional data. The cost figures are therefore given in terms of the cost for the material included in the 1,610 materials plus the additional cost if the registration is one of the 800 modified technicals or concentrates.

3/ Data for this submission would be generated under Product Analytical Methods and Product Analytical Data.

Note: Not all existing products with registrations will be reregistered. For this reason, the total costs in the above table are not a good indication of total projected future costs. Such projections are provided later in this report, i.e., Section IV.

Table 2

Comparison of the Cost of Product Chemistry Requirements for New Active Ingredients 2/ Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent 1/ of A.I.'s 2/ Requiring Data Submission		Cost of Data Submission		Cost Per Average A.I. 2/		
	Current (%)	Guidelines (%)	Current ($)	Guidelines 3/ ($)	Current ($)	Guidelines ($)	Difference ($)
Description of Manufacturing Process	100.0	100.0	250	1,050	250	1,050	800
Discussion of Unintentional Ingredients	0.0	100.0	0	113	0	113	113
Product Analytical Methods	100.0	100.0	55,000	61,000	55,000	61,000	6,000
Product Analytical Data	100.0	100.0	300	2,400	300	2,400	2,100
Declaration/Certification of Limits	0.0	100.0	0	100	0	100	100
Physical/Chemical Properties	100.0	100.0	1,500	2,400	1,500	2,400	900
				Totals	57,050	67,063	10,013

1/ The percentage of new A.I.'s requiring a test is assumed to be the same as for the A.I.'s in currently registered products.

2/ The product registered would be a manufacturing-use product or formulation. The material requiring test or data submission could be a manufacturing-use product or form of an active ingredient.

3/ These costs are weighted to reflect the fact that some manufacturing-use products are different from the technical grade of the active ingredient and hence additional data may be needed.

Table 3

Comparison of the Cost of Product Chemistry Requirements for New Formulated Products Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent 1/ of A.I.'s Requiring Data Submission		Cost of Data Submission		Cost Per Average A.I.		
	Current (%)	Guidelines (%)	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Description of Manufacturing Process	100.0	100.0	250	1,000	250	1,000	750
Discussion on Unintentional Ingredients	0.0	100.0	0	100	0	100	100
Product Analytical Methods	9.0	9.0	10,000	10,000	900	900	0
Product Analytical Data	100.0	100.0	300	1,600	300	1,600	1,300
Physical/Chemical Properties	100.0	100.0	1,500	1,600	1,500	1,600	100
				Totals	2,950	5,200	2,250

1/ The percentage of new formulations requiring a test is assumed to be the same as for the formulations currently registered.

Table 4

Number and Cost of Tests for Environmental Chemistry:
Comparison of Current Practice with Proposed Guidelines
Applied to Reregistration

Proposed Guidelines Requirement	Material Tested[1/]	Number of Tests		Cost Per Test		Totals		Difference ($000's)
		Current Practice	Guidelines	Current Practice ($)	Guidelines ($)	Current Practice ($000's)	Guidelines ($000's)	
Hydrolysis	Tech[5/]	1,463	1,463	12,000	12,000	17,556	17,556	0
Photodegradation	Tech[5/]	1,045	1,045	20,000	20,000	20,900	20,900	0
Aerobic Soil Metabolism	Tech[5/]	975	975	29,000	29,000	28,275	28,275	0
Anaerobic Soil Metabolism	Tech[5/]	975	975	2,900[2/]	2,900[2/]	2,828	2,828	0
Anaerobic Aquatic Metabolism	AI	125	125	25,000	25,000	3,125	3,125	0
Aerobic Aquatic Metabolism	AI	125	125	25,000	25,000	3,125	3,125	0
Effects of Microbes on Pesticides	Tech[5/]	980	980	28,000	28,000	27,440	27,440	0
Effects of Pesticides on Microbes	Tech	980	980	28,000	28,000	27,440	27,440	0
Activated Sludge Metabolism	AI	1,000	1,000	15,000	15,000	15,000	15,000	0
Leaching	Tech[5/]	995	995	10,000	10,000	9,950	9,950	0
Volatility	Tech	100	100	7,500	7,500	750	750	0
Adsorption/Desorption	Tech[5/]	1,010	1,010	7,500	7,500	7,575	7,575	0
Water Dispersal	Form	188	188	16,000	16,000	3,008	3,008	0
Field Dissipation-Soil	Form	1,363	1,363	29,000	29,000	35,527	35,527	0
Field Dissipation-Water	Form	150	150	21,000	21,000	3,150	3,150	0
Forest Dissipation	Form	56	56	50,000	50,000	2,800	2,800	0
Combination and Tank Mix	Form	150	150	9,000[3/]	9,000[3/]	1,350	1,350	0
Long Term Accumulation Study	Form	155	155	20,000[4/]	20,000[4/]	3,100	3,100	0
Rotational Crop	AI	500	500	20,000[4/]	20,000[4/]	10,000	10,000	0
Irrigated Crops	Form	50	50	20,000	20,000	1,000	1,000	0
Fish Accumulation	Tech[5/]	905	905	20,000	20,000	18,100	18,100	0
						241,999	241,999	0

1/ Tech - technical grade of active ingredient
AI - active ingredient which may be radioactive-labeled
Form - representative formulated product
2/ In addition to aerobic soil metabolism
3/ In addition to Field-Dissipation-Soil Test
4/ Assume 4 crops
5/ These tests may also be conducted with a radioactive-labeled active ingredient.

Note: Not all existing products with registrations will be reregistered. For this reason, the total costs in the above table are not a good indication of total projected future costs. Such projections are provided later in this report, i.e., Section IV.

Table 5

Comparison of the Cost of Environmental Chemistry Requirements for New Active Ingredients[2/] Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent[1/] of A.I.'s[2/] Requiring Test		Cost of Test		Cost Per Average A.I.[2/]		
	Current (%)	Guidelines (%)	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Hydrolysis	100.0	100.0	12,000	12,000	12,000	12,000	0
Photodegradation	71.0	71.0	20,000	20,000	14,200	14,200	0
Aerobic Soil Metabolism	67.0	67.0	29,000[3/]	29,000[3/]	19,430	19,430	0
Anaerobic Soil Metabolism	67.0	67.0	2,900[3/]	2,900[3/]	1,943	1,943	0
Anaerobic Aquatic Metabolism	8.5	8.5	25,000	25,000	2,125	2,125	0
Aerobic Aquatic Metabolism	8.5	8.5	25,000	25,000	2,125	2,125	0
Effects of Microbes on Pesticides	67.0	67.0	28,000	28,000	18,760	18,760	0
Effects of Pesticides on Microbes	67.0	67.0	28,000	28,000	18,760	18,760	0
Activated Sludge Metabolism	68.0	68.0	15,000	15,000	10,200	10,200	0
Leaching	68.0	68.0	10,000	10,000	6,800	6,800	0
Volatility	6.8	6.8	7,500	7,500	510	510	0
Adsorption/Desorption	69.0	69.0	7,500	7,500	5,175	5,175	0
Rotational Crop	34.0	34.0	20,000	20,000	6,800	6,800	0
Fish Accuumulation	62.0	62.0	20,000	20,000	12,400	12,400	0
				Totals	131,228	131,228	0

1/ The percentage of new A.I.'s requiring a test is assumed to be the same as for the A.I.'s in currently registered products.
2/ The product registered would be a manufacturing-use product or formulation. The material used in the testing would be either technical grade of the active ingredient, the active ingredient, or radiolabelled active ingredient.
3/ In addition to aerobic soil metabolism test.

Table 6

Comparison of the Cost of Environmental Chemistry Requirements for New Formulated Products Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent[1/] of Products Requiring Test		Cost of Test		Cost Per Average Product		
	Current (%)	Guidelines (%)	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Water Dispersal	0.6	0.6	16,000	16,000	96	96	0
Field Dissipation-Soil	4.4	4.4	29,000	29,000	1,276	1,276	0
Field Dissipation-Water	0.5	0.5	21,000	21,000	105	105	0
Forest Dissipation	0.1	0.1	50,000	50,000	50	50	0
Combination and Tank Mix	0.5	0.5	9,000	9,000	45	45	0
Long Term Study	0.5	0.5	20,000[2/]	20,000[2/]	100	100	0
Irrigated Crops	0.2	0.2	20,000	20,000	40	40	0
				Totals	1,712	1,712	0

1/ The percent of new formulations requiring a test is assumed to be the same as for currently registered formulations.
2/ In addition to Field Dissipation-Soil Test.

Table 7

Number and Costs of Tests for Special Chemistry:
Comparison of Current Practice with Proposed Guidelines
Applied to Reregistration

Proposed Guidelines Requirement	Material Tested[1/]	Number of Tests		Cost Per Test		Totals		Difference ($000's)
		Current Practice	Guidelines	Current Practice ($)	Guidelines ($)	Current Practice ($000's)	Guidelines ($000's)	
Residue Analysis on Green Tobacco	A.I.	21	21	50,000	50,000	1,050	1,050	0
Residue Analysis on Dry Tobacco	A.I.	3	3	20,000[2/]	20,000[2/]	60[2/]	60[2/]	0
Residue Analysis in Smoke Including Pyrolysis Products	A.I.	1	1	80,000[3/]	80,000[3/]	80[3/]	80[3/]	0
						1,190	1,190	0

1/ A.I. - Active Ingredient
2/ In addition to residue analysis on green tobacco
3/ In addition to residue analysis on green and dry tobacco

Note: Not all existing products with registrations will be reregistered. For this reason, the total costs in the above table are not a good indication of total projected future costs. Such projections are provided later in this report, i.e., Section IV.

Table 8

Comparison of the Cost of Special Chemistry Requirements for Active Ingredients[2/]
Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent[1/] of A.I.'s[2/] Requiring Test		Cost of Test		Cost Per Average A.I.[2/]		
	Current (%)	Guidelines (%)	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Residue Analysis on Green Tobacco	1.4	1.4	50,000	50,000	700	700	0
Residue Analysis on Dry Tobacco	0.2	0.2	20,000	20,000	40	40	0
Residue Analysis in Smoke Including Pyrolysis Products	0.07	0.07	80,000	80,000	56	56	0
				Totals	796	796	0

1/ The percentage of new active ingredients requiring a test is assumed to be the same as for the active ingredients in currently registered products.
2/ The product registered would be a manufacturing use product or a formulation. The material used in testing would likely be a radio-labelled active ingredient.

Table 9

Number and Cost of Tests for Fish and Wildlife Hazard:
Comparison of Current Practice with Proposed Guidelines
Applied to Reregistration

Proposed Guidelines Requirement	Material Tested 1/	Number of Tests		Cost Per Test		Totals		Difference ($000's)
		Current Practice	Guidelines	Current Practice ($)	Guidelines ($)	Current Practice ($000's)	Guidelines ($000's)	
Avian Single Dose LD50	Tech	1,463	1,463	1,500	1,500	2,195	2,195	0
Avian Dietary LC50	Tech	1,463	1,463	2,000	2,000	2,926	2,926	0
Mammalian Acute Toxicity	Tech	60	95	1,000	1,000	60	95	35
Avian Reproduction	Tech	112	167	24,000	24,000	2,688	4,008	1,320
Small Pen Study	Form	61	126	12,000	12,000	732	1,512	780
Large Pen Study	Form	15	60	25,000	25,000	375	1,500	1,125
Field Test	Form	27	29	50,000	50,000	1,350	1,450	100
Fish Acute LC50	Tech	1,463	1,463	750	750	1,097	1,097	0
Fish Acute LC50	Form	236	2,502	750	750	177	1,877	1,700
Acute Toxicity to Aquatic Invertebrates	Tech	1,463	1,463	360	360	527	527	0
	Form	236	2,502	360	360	85	901	816
Acute Toxicity to Estuarine & Marine Organisms	Tech	198	270	1,450	1,800	287	486	199
Acute Toxicity to Estuarine & Marine Organisms	Form	220	502	1,450	1,800	319	904	585
Fish Reproduction or Invertebrate Life-cycle	Tech	185	185	11,500	11,500	2,128	2,128	0
Fish Embryo-larvae Test	Tech	39	92	40,000	40,000	1,560	3,680	2,120
Aquatic Organism Toxicity & Residue Study	Tech	18	90	20,000	20,000	360	1,800	1,440
Simulated or Actual Field Testing for Aquatic Organisms	Form	64	70	200,000	200,000	12,800	14,000	1,200
						29,666	41,086	11,420

1/ Tech - Technical Grade of Active Ingredient
Form - Formulated Product

Note: Not all existing products with registrations will be reregistered. For this reason, the total costs in the above table are not a good indication of total projected future costs. Such projections are provided later in this report, i.e., Section IV.

Table 10

Comparison of the Cost of Fish and Wildlife Hazard Requirements for New Active Ingredients[2/] Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent[1/] of A.I.'s[2/] Requiring Test		Cost of Test		Cost Per Average A.I.[2/]		
	Current (%)	Guidelines (%)	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Avian Single Dose LD50	100.0	100.0	1,500	1,500	1,500	1,500	0
Avian Dietary LC50	100.0	100.0	2,000	2,000	2,000	2,000	0
Mammalian Acute Toxicity	4.1	6.5	1,000	1,000	41	65	24
Avian Reproduction	7.7	11.4	24,000	24,000	1,848	2,736	888
Fish Acute LC50	100.0	100.0	750	750	750	750	0
Acute Toxicity to Aquatic Invertebrates	100.0	100.0	360	360	360	360	0
Acute Toxicity to Estuarine & Marine Organisms	13.5	18.5	1,450	1,800	196	333	137
Fish Reproduction or Invertebrate Life-Cycle	12.7	12.7	11,500	11,500	1,460	1,460	0
Fish Life Cycle Test	2.7	6.2	40,000	40,000	1,080	2,480	1,400
Aquatic Organism Toxicity & Residue Study	1.2	6.2	20,000	20,000	240	1,240	1,000
				Totals	9,475	12,924	3,449

1/ The percentage of new active ingredients requiring a test is assumed to be the same as for the active ingredients in currently registered products.

2/ The product registered would be a manufacturing-use product or formulated product. The material used in the testing would be a technical grade of the active ingredient.

Table 11

Comparison of the Cost of Fish and Wildlife Hazard Requirements for New Formulated Products Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent[1/] of Products Requiring Test		Cost of Test		Cost Per Average Product		
	Current (%)	Guidelines (%)	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Small Pen Study	0.2	0.4	12,000	12,000	24	48	24
Large Pen Study	0.05	0.2	25,000	25,000	13	50	37
Field Test	0.087	0.093	50,000	50,000	44	47	3
Fish Acute LC50	0.8	8.0	750	750	6	60	54
Acute Toxicity to Estuarine & Marine Organisms	0.7	1.6	1,450	1,800	10	29	19
Acute Toxicity to Aquatic Invertebrates	0.8	8.0	360	360	3	29	26
Simulated or Actual Field Testing for Aquatic Organisms	0.21	0.22	200,000	200,000	420	440	20
				Totals	520	703	183

1/ The percentage of new formulated products requiring a test is assumed to be the same as for the currently registered products.

Table 12

Number and Cost of Tests for Human Hazard Evaluation:
Comparison of Current Practice with Proposed Guidelines
Applied to Reregistration

Proposed Guidelines Requirement	Material Tested	Number of Tests		Cost per Test		Total		Difference ($1,000's)
		Current Practice	Guidelines	Current Practice (Dollars)	Guidelines (Dollars)	Current Practice ($1,000's)	Guidelines ($1,000's)	
Acute Oral Toxicity	MUP	1,585	1,585	700	700	1,100	1,100	0
Acute Oral Toxicity	FP	31,140	31,140	700	700	21,798	21,798	0
Acute Oral Toxicity	DL	0	3,000	700	700	0	2,100	2,100
Acute Oral Toxicity	AI	0	400	700	700	0	280	280
Acute Dermal Toxicity	MUP	1,585	1,585	650	1,300	1,030	2,060	1,030
Acute Dermal Toxicity	FP	31,140	31,140	650	1,300	20,241	40,482	20,241
Acute Dermal Toxicity	AI	0	400	650	1,300	0	845	845
Acute Inhalation Toxicity	MUP	220	220	750	1,500	165	330	165
Acute Inhalation Toxicity	FP	23,400	23,400	750	1,500	17,550	35,100	17,550
Acute Inhalation Toxicity	AI	2	2	750	1,500	2	3	1
Primary Eye Irritation	MUP	1,595	1,595	550	550	877	877	0
Primary Eye Irritation	FP	30,885	30,885	550	550	16,987	16,987	0
Primary Dermal Irritation	MUP	1,595	1,595	400	400	638	638	0
Primary Dermal Irritation	FP	30,885	30,885	400	400	12,354	12,354	0
Dermal Sensitization	MUP	16	1,610	400	400	6	644	638
Dermal Sensitization	FP	15,600	15,600	400	400	6,240	6,240	0
Acute Delayed Neurotoxicity	AI	90	100	5,000	5,000	450	500	50
Subchronic Oral Dosing	AI	354	354	75,000	75,000	26,550	26,550	0
21-day Dermal Toxicity	AI	300	400	20,000	20,000	6,000	8,000	2,000
90-day Dermal Toxicity	AI	0	15	25,000	25,000	0	375	375
Subchronic Inhalation Toxicity	AI	5	167	12,000	120,000	60	20,040	19,980
Subchronic Neurotoxicity	AI	0	6	12,000	12,000	0	72	72
Chronic Feeding	AI	344	354	75,000	150,000 [2/]	25,800	53,100	27,300
Oncogenicity	AI	460	460	80,000	162,000 [2/]	36,800	74,520	37,720
Teratogenicity	AI	344	490	9,500	30,000	3,268	14,700	11,432
Reproduction	AI	344	490	30,000	30,000	10,320	14,700	4,380
Mutagenicity	AI	344	490	55,000	55,000	18,920	26,950	8,030
Metabolism-Single Dose	AI [1/]	172	500	4,000	4,000	688	2,000	1,312
Metabolism-Multiple Dose	AI [1/]	172	344	10,000	10,000	1,720	3,440	1,720
					Totals	229,564	386,785	157,221

1/ Radiolabeled A.I. is normally required

2/ In addition to cost of Chronic Feeding.

Note: Not all existing products with registrations will be reregistered. For this reason, the total costs in the above table are not a good indication of total projected future costs. Such projections are provided later in this report, i.e., Section IV.

Table 13

Comparison of the Cost of Human Hazard Evaluation Requirements for New Active Ingredients[2/] Under Current Practice and Proposed Guidelines

	Percent[1/] of AI's[2/] Requiring Data Submission		Cost of Testing		Cost per Average Product		
	Current	Guidelines	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Acute Oral Toxicity [3/]	98	98	700	875	686	858	172
Acute Dermal Toxicity [3/]	98	98	650	1,625	637	1,593	956
Acute Inhalation Toxicity	15	15	750	1,500	113	225	112
Primary Eye Irritation	99	99	550	550	545	545	0
Primary Dermal Irritation	99	99	400	400	396	396	0
Dermal Sensitization	1	100	400	400	4	400	396
Acute Delayed Neurotoxicity	6	7	5,000	5,000	300	350	50
Subchronic Oral Dosing	24	24	75,000	75,000	18,000	18,000	0
21-Day Dermal Toxicity	21	27	20,000	20,000	4,200	5,400	1,200
90-Day Dermal Toxicity	0	1	25,000	25,000	0	250	250
Subchronic Inhalation Toxicity	1	11	12,000	120,000	120	13,200	13,080
Subchronic Neurotoxicity	0	1	12,000	12,000	0	120	120
Chronic Feeding	23	24	75,000	150,000	17,250	36,000	18,750
Oncogenicity	31	31	80,000	162,000	24,800	50,220	25,420
Teratogenicity	23	33	9,500	30,000	2,185	9,900	7,715
Reproduction	23	33	30,000	30,000	6,900	9,900	3,000
Mutagenicity	23	33	55,000	55,000	12,650	18,150	5,500
Metabolism-Single Dose	12	34	4,000	4,000	480	1,360	880
Metabolism-Multiple Dose	12	24	10,000	10,000	1,200	2,400	1,200
				Totals	90,466	169,267	78,801

1/ The percentage of active ingredients requiring a test is assumed to be the same as for the active ingredients in currently registered products.

2/ The product registered would be a manufacturing-use product or a formulated product. The material tested would be a form of the active ingredient.

3/ The cost figures for these tests are weighted to include an additional 25% for those active ingredients requiring additional testing where the manufacturing-use product differs from the technical grade of the active ingredient.

Table 14

Comparison of the Cost of Human Hazard Evaluation Requirements for New Formulated Products Under Current Practice and Proposed Guidelines

Proposed Guidelines Requirement	Percent of Products[1/] Requiring Test		Cost of Test		Cost per Average Product		
	Current	Guidelines	Current ($)	Guidelines ($)	Current ($)	Guidelines ($)	Difference ($)
Acute Oral Toxicity [2/]	99	99	700	770	693	762	69
Acute Dermal Toxicity	99	99	650	1,300	644	1,288	644
Acute Inhalation Toxicity	75	75	750	1,500	563	1,126	563
Primary Eye Irritation	99	99	550	550	545	545	0
Primary Dermal Irritation	99	99	400	400	396	396	0
Dermal Sensitization	50	50	400	400	200	200	0
				Totals	3,041	4,317	1,276

1/ The percentage of new formulated products requiring a test is assumed to be the same as for formulated products currently registered.

2/ The cost of this study is weighted to include an additional 10% for those products requiring additional testing on the use dilution.

Table 15

Total Data Cost of Guidelines Applied to Reregistration Broken Down by Components

Guidelines Section	Total Data Cost of Guidelines ($000's)	Incremental[1/] Data Cost of Guidelines ($000's)	Total Data Cost of Current Practice ($000's)	Value of Acceptable Data ($000's)	Cost to Meet Data Gaps ($000's)	Incremental Data Cost as Percent of Total Data Cost (%)	Cost of Current Practice as Percent of Total Data Cost (%)	Value of Acceptable Data as Percent of Total Data Cost (%)	Cost of Data Gaps as Percent of Total Data Cost (%)
Product Chemistry	278,203	89,901	188,302	13,910	174,392	32.3	67.7	5.0	62.7
Environmental Chemistry	241,999	0	241,999	12,100	229,899	0	100.0	5.0	95.0
Special Chemistry	1,190	0	1,190	119	1,071	0	100.0	10.0	90.0
Fish & Wildlife Hazard	41,086	11,420	29,666	8,217	21,449	27.8	72.2	20.0	52.2
Human and Domestic Animal Hazard	386,785	157,221	229,564	116,035	113,429	40.7	59.3	30.0	29.4
Total	949,263	258,542	690,721	150,381	540,240	27.2	72.8	15.8	57.0

1/ Incremental is defined as cost of guidelines minus cost of current practice

Note: Not all existing products with registrations will be reregistered. For this reason, the total costs in the above table are not a good indication of total projected future costs. Such projections are provided later in this report, i.e., Section IV.

Table 16

Total Data Costs for Typical New Registrations Under Current Practice and the Guidelines

Guidelines Section		Total Data Cost Current Practice ($)	Total Data Cost Guidelines ($)
Product Chemistry	AI	57,050	67,063
	Formulation	2,950	5,200
Environmental Chemistry	AI	131,228	131,228
	Formulation	1,712	1,712
Special Chemistry	AI	796	796
Fish & Wildlife Hazard	AI	9,475	12,924
	Formulation	520	703
Human & Domestic Animal Hazard	AI	90,466	169,267
	Formulation	3,041	4,317
Total	AI	289,015	381,278
	Formulation	8,223	11,932

Table 17

Summary of Annual Cost for Guidelines and Current Practice Applied to Reregistration Under the Generic Standards Concept for Scenario #1

Years	Tech. A.I. Standards Issued		A.I.'s Committed to Registration				A.I.'s Withdrawn by Registrant			
			Current		Guidelines		Current		Guidelines	
	New	Total	New	Total	New	Total	New	Total	New	Total
1979	50	50	--	--	--	--	--	--	--	--
1980	50	100	50	50	50	50	0	0	0	0
1981	50	150	50	100	50	100	0	0	0	0
1982	50	200	50	150	45	145	0	0	5	5
1983	50	250	45	195	40	185	5	5	10	15
1984	50	300	40	235	40	225	10	15	10	25
1985	50	350	40	275	40	265	10	25	10	35
1986	50	400	40	315	35	300	10	35	15	50
1987	50	450	35	350	35	335	15	50	15	65
1988	50	500	35	385	30	365	15	65	20	85
1989	50	550	35	420	30	395	15	80	20	105

Additional [1/] Data Cost [2/] Per A.I. [3/] for A.I.'s Under Standards Issued in Years:

Years	(T-1)		(T-2)		(T-3)		(T-4)		Total Annual Costs		
	Current	Guidelines	Current	Guidelines	Current	Guidelines	Current	Guidelines	Current ($000's)	Guidelines ($000's)	Difference ($000's)
	$000's										
1979	0	0	0	0	0	0	0	0	0	0	0
1980	175	280	0	0	0	0	0	0	8,750	14,000	5,250
1981	175	280	175	280	0	0	0	0	17,500	28,000	10,500
1982	175	280	175	280	175	280	0	0	26,250	40,600	14,350
1983	150	240	175	280	175	280	175	280	33,000	50,200	17,200
1984	150	240	150	240	175	280	175	280	31,375	45,800	14,425
1985	150	240	150	240	150	240	175	280	28,625	41,400	12,775
1986	113	150	150	240	150	240	150	240	23,270	34,050	10,780
1987	113	150	113	150	150	150	150	240	20,475	26,100	5,625
1988	113	150	113	150	113	150	150	240	18,430	24,600	6,170
1989	63	84	113	150	113	150	113	150	14,635	17,250	2,615

[1/] The cost figures have been adjusted for data meeting the requirements of the guidelines previously submitted to the Agency.
[2/] See Appendix C for details on derivations of costs.
[3/] The cost figures include the cost of data that must be submitted on formulations containing the active ingredient. Based upon the cost analysis it is estimated that data on formulations would add 25% and 40% to the cost of data on active ingredients under current practice and the guidelines respectively. The costs are assumed to be incurred linearly over 4 years.

Table 18

Summary of Annual Cost for Guidelines and Current Practice Applied to Reregistration Under the Generic Standards Concept for Scenario #2

Years	Early Notifications Issued	Tech. A.I. Standards Issued	A.I.'s Committed to Registration				A.I.'s Withdrawn by Registrant			
			Current		Guidelines		Current		Guidelines	
			New	Total	New	Total	New	Total	New	Total
1979	100	50								
1980	100	50	100	100	100	100	0	0	0	0
1981	100	50	95	195	85	185	5	5	15	15
1982	100	50	80	275	80	265	20	25	20	35
1983	100	50	75	350	70	335	25	50	30	65
1984		50	70	420	60	395	30	80	40	105
1985		50	30	450	30	425	20	100	20	125
1986		50	30	480	25	450	20	120	25	150
1987		50	30	510	25	475	20	140	25	175
1988		50	25	535	25	500	25	165	25	200
1989		50	25	560	25	525	25	190	25	225

Additional [1] Data Cost [2] Per A.I. [3] for A.I.'s Under Standards for Notifications Issued in Years

Years	(T-1)		(T-2)		(T-3)		(T-4)		Total Annual Costs		
	Current	Guidelines	Current	Guidelines	Current	Guidelines	Current	Guidelines	Current ($000's)	Guidelines ($000's)	Difference ($000's)
	$000's										
1979									0	0	0
1980	175	280	0	0	0	0	0	0	17,500	28,000	10,500
1981	163	260	175	280	0	0	0	0	32,985	50,100	17,115
1982	150	240	163	260	175	280	0	0	44,985	69,300	24,315
1983	113	150	150	240	163	260	175	280	53,460	79,800	26,340
1984	88	117	113	150	150	240	163	260	42,120	58,820	16,700
1985	63	84	88	117	113	150	150	240	28,525	39,240	10,715
1986	63	84	63	84	88	117	113	150	18,415	22,140	3,725
1987	50	84	63	84	63	84	88	117	11,440	13,740	2,300
1988	50	84	50	84	63	84	63	84	6,530	8,820	2,290
1989	50	84	50	84	50	84	63	84	5,890	8,400	2,510

[1] The cost figures have been adjusted for data meeting the requirements of the guidelines previously submitted to the Agency.
[2] See Appendix C for details on derivations of costs.
[3] The cost figures include the cost of data that must be submitted on formulations containing the active ingredient. Based upon the cost analysis it is estimated that data on formulations would add 25% and 40% to the cost of data on active ingredients under current practice and the guidelines respectively. The costs are assumed to be incurred linearly over 4 years.

Table 19 Projections of Costs to Complete Reregistration Under Scenarios #1 and #2

	No. A.I.'s	Costs				
		Current Practice	Guide-lines	Incre-mental	Acceptable Data	Projected Actual Outlays
		$ Millions				
Scenario #1:						
Products now in production						
1. Reregistered during first 10 years	395	281	381	100	59	322
2. Not reregistered during first 10 years	105	75	101	26	16	0
3. Subtotal (10 years)	500	356	482	126	75	322
4. Remainder to be reregistered or not reregistered later	500[1/]	243	352	109	50	151[1/]
5. Subtotal	1,000	599	834	235	125	473
6. Products not now in production (Assumed to not be reregistered)	460	92	115	24	25	0
7. Grand Total	1,460	691	949	259	150	473
Scenario #2:						
Products now in production						
1. Reregistered during first 10 years	525	332	446	114	70	376
2. Not reregistered during first 10 years	225	145	212	67	33	0
3. Subtotal (10 years)	750	477	658	181	103	376
4. Remainder to be reregistered or not reregistered later	250[2/]	122	176	54	22	97[2/]
5. Subtotal	1,000	599	834	235	125	473
6. Products not now in production (Assumed to not be reregistered)	460	92	115	24	25	0
7. Grand Total	1,460	691	949	259	150	473

1/ Assumption made is that 250 of 500 A.I.'s in this group will eventually be reregistered.

2/ Assumption made is that 120 of 250 A.I.'s in this group will eventually be reregistered.

Table 20

Projected Annual Costs of Meeting Guidelines Requirements Under Two Alternative Registration Scenarios, 1980-89, 1977 Prices

Registration Scenario & Type of Costs	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
	$ millions									
Scenario #1 (50 Generic Stds/Yr)										
Reregistration										
Incremental	5	11	14	17	14	13	11	6	6	3
Data Gaps	9	18	26	33	31	29	23	20	18	15
Total	14	29	40	50	45	42	34	26	24	18
New Registrations										
Incremental	12	12	12	12	12	12	12	12	12	12
Current Requirements	27	27	27	27	27	27	27	27	27	27
Total	39	39	39	39	39	39	39	39	39	39
All Registrations										
Incremental Only	17	23	26	29	26	25	23	18	18	15
Data Gaps/Current Requirements	36	45	53	60	58	56	50	47	45	42
Total	53	68	79	89	84	81	73	65	63	57
Scenario #2 (50 Generic Stds/Yr with early notification)										
Reregistration										
Incremental	10	17	24	26	17	11	3	2	2	2
Data Gaps	18	33	45	53	42	28	18	11	7	6
Total	28	50	69	79	59	39	21	13	9	8
New Registrations										
Incremental	12	12	12	12	12	12	12	12	12	12
Current Requirements	27	27	27	27	27	27	27	27	27	27
Total	39	39	39	39	39	39	39	39	39	39
All Registrations										
Incremental Only	22	29	36	38	29	23	15	14	14	14
Data Gaps/Current Requirements	45	60	72	80	69	55	45	38	34	33
Total	67	89	108	118	98	78	60	52	48	47

Table 21

Comparison of Projected Annual Costs of Meeting Guidelines Requirements with Domestic Pesticide Sales and with Pesticides Industry R&D, 1980-89 Projections, by Alternative Registration Scenario

Sales, Cost and Comparison	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
Domestic pesticide sales[1/] ($ million)	2,381	2,476	2,575	2,678	2,785	2,897	3,013	3,133	3,259	3,389
Pesticides R&D costs[2/] for domestic sales ($ million)										
Total	167	173	180	187	195	203	211	219	228	237
Registration-related [3/]	48	50	52	54	56	58	60	63	65	68
Costs of Scenario #1										
Incremental only: cost ($ million)	17	23	26	29	26	25	23	18	18	15
Compared to sales (%)	0.7	0.9	1.0	1.1	0.9	0.9	0.8	0.6	0.6	0.4
Compared to total R&D (%)	10.2	13.3	15.0	15.5	13.9	12.3	10.9	8.2	7.9	6.3
Compared to registration-related R&D (%)	35.4	46.0	50.0	53.7	46.4	43.1	38.3	28.6	27.7	22.1
Including data gaps: cost ($ million)	53	68	79	89	84	81	73	65	63	57
Compared to sales (%)	2.3	2.8	3.1	3.3	3.0	2.8	2.4	2.1	1.9	1.7
Compared to total R&D (%)	31.7	39.3	43.9	47.6	43.1	39.9	34.6	29.7	27.6	24.1
Compared to registration-related R&D (%)	110.4	136.0	151.9	164.8	150.0	139.7	212.7	103.2	96.9	83.8
Costs of Scenario #2										
Incremental only: cost ($ million)	22	29	36	38	29	23	15	14	14	14
Compared to sales (%)	0.9	1.2	1.4	1.4	1.0	0.8	0.5	0.5	0.4	0.4
Compared to total R&D (%)	13.2	16.8	19.3	20.3	14.9	11.3	7.1	6.4	6.1	5.9
Compared to registration-related R&D (%)	45.8	58.0	69.2	70.4	51.8	39.7	25.0	22.2	21.5	20.6
Including data gaps: cost ($ million	67	89	108	118	98	78	60	52	48	47
Compared to sales (%)	2.8	3.6	4.2	4.4	3.5	2.7	2.0	1.7	1.5	1.4
Compared to total R&D (%)	40.1	51.5	60.0	63.1	50.3	38.4	28.4	23.7	21.1	19.8
Compared to registration-related R&D (%)	139.6	178.0	207.7	218.5	175.0	134.5	100.0	82.5	73.9	69.1

[1/] Domestic sales = domestic sales of domestic production + sales of imports. Annual increase projected at 4% in real terms from a base of $2,035 million in 1976.

[2/] Calculated as equivalent to 7% of domestic pesticide sales in corresponding years.

[3/] Calculated as equivalent to 2% of domestic pesticide sales in corresponding years. Do not include additional R&D costs resulting from the guidelines.

Table 11 shows similar estimates for new formulations. The incremental cost of the guidelines for average new formulations registered each year would be $183 per product. The 2,800 new formulations translate into an incremental cost of $512,400 for the guidelines as compared to current practice.

Appendix D contains a tabular presentation of the Agency's rationale for changing the data requirements from those for current practice to those in the proposed guidelines.

E. HUMAN AND DOMESTIC ANIMAL HAZARD

The guidelines, subpart F Hazard Evaluation: Humans and Domestic Animals, are designed to generate data on the toxicity of a pesticide product. Data are required on both short term effects such as acute toxicities through various exposure paths and also long term or chronic exposure effects such as oncogenicity. Table 12 provides estimates for reregistration of the costs attributable to the guidelines and under current practice. The difference or incremental costs are calculated to be $157.2 million.

Table 13 shows that under the guidelines, human hazard data for an average new active ingredient would cost $78,801 more to submit than under the current practice. Under the assumption that products containing 15 new active ingredients would be registered each year, the incremental annual cost for new active ingredients would be $1.18 million.

Table 14 provides the estimates used to calculate the incremental cost of subpart F for average new formulations registered each year. The $1,276 per product and the estimated 2,800 new formulations translate into an incremental cost of $3.57 million for the guidelines as compared to current practice.

Appendix D contains a tabular presentation of the Agency's rationale for changing the data requirements from those for current practice to those in the proposed guidelines.

F. DATA RETENTION

Subpart B would require applicants and registrants to retain and make available raw data, specimens, and samples of test material concerning data submitted to the Agency. This requirement clarifies these existing requirements in 40 CFR 169.2(k)(1) pertaining to retention of research data. The guidelines specifically define the kinds of "research data" which must be kept and identify the period of retention.

The Office of Pesticide Programs has initiated a lab audit program to review data which served as the basis for the toxicology testing results submitted to the Agency. At one informal hearing on this subject, the finding was that labs, as a general practice, retain the raw data presently and, in fact, regard the data as their property (EPA, 1977). The registrants accordingly should be able to arrange for Agency access to the data. Therefore, the requirement of record retention should not increase costs in most instances since the storage costs are likely already covered by overhead charges.

G. SUMMARY OF INCREMENTAL COSTS

The incremental one-time costs of the guidelines for subparts B, D, E, and F equal $258 million for reregistration of all existing products. (As will be discussed later, principally in section VI, many existing products with registrations will not be reregistered thus reducing the data costs for reregistration below $258 million.) The incremental costs of the guidelines for new registrations are estimated to be about $11.7 million per year. The breakdown by topic areas in the guidelines is as follows:

[In thousands]

	1-time incremental reregistration costs	Annual incremental cost for new registrations
Product chemistry	$89,901	$6,400
Environmental chemistry	0	0
Special chemistry	0	0
Fish and wildlife	11,420	564
Human and domestic animal hazard	157,221	4,752
Total	258,542	11,716

These basic cost estimates, along with those to meet current practice requirements [including data gaps which are reported in the next section of this report (part V)] are utilized in the economic impact analysis (part VI).

V. TOTAL PROJECTED COST OF GUIDELINES

A. REREGISTRATION

The total cost of data for reregistration can be broken down into three components: (1) The incremental cost of the guidelines; (2) the cost of submitting data to meet current standards, i.e. filling "data gaps"; and (3) the value in current prices of acceptable data already submitted to EPA in support of a registration.

The incremental cost of the guidelines has already been explained. The last two components of the total data cost require further explanation. The sum of these two components would be the total cost of data for reregistration under current practice or the "non-incremental" cost of the guidelines. A data gap in existing files would result either because data required under current practice have never been submitted to the Agency in support of a registration or because data on file are no longer scientifically acceptable, given the current state of the art of testing. Although a detailed product-by-product review of data available to EPA has not been conducted, the Agency estimated the amount of available data which would satisfy the purposes of the requirements of the guidelines. The estimates are not exact and therefore only approximate the amount of acceptable data which is already available.

Table 15 summarizes the total data cost of reregistration including the three components discussed above. The total data cost for reregistration equals $949 million, of which $259 million are incremental costs and about $691 million (73 percent) are the costs of the data requirements under current practice. Presently, an estimated 78 percent of the current requirements have not been met ($540 million out of $691 million) by submissions to EPA. No doubt some of these data have been generated, even though not yet submitted to EPA. Filling of data gaps which would occur under current practice account for 57 percent of the total data cost ($540 million out of $949 million). The guidelines would increase the cost of reregistration by approximately one-half (from $691 million to $949 million), if all presently registered products were to be reregistered.

The data cost of $949 million for reregistration is not expected to actually be incurred because not all presently registered products are expected to be reregistered. Rather, the costs will be substantially less, as indicated in section VI where two alternative reregistration scenarios are used to project actual costs.

B. NEW REGISTRATIONS

The total cost of the data for a new registration was developed in the process of calculating the incremental cost of the guidelines. Table 16 summarizes the cost for the new registration of typical products under the guidelines and under current practice. Some costs result from tests with the active ingredient, either in a manufacturing-use product or some other technical form. Other costs result from tests with a formulated product. The figures in table 16 are extracted from tables 2, 3, 5, 6, 8, 10, 11, 13, and 14.

The total cost for data under the guidelines derived from testing active ingredients would be $381,278 as compared to $289,015 under current practice. Using the previously-assumed estimate that 15 new active ingredients would be registered in a typical year, the total data cost for new active ingredients would be $5.7 million as com-

pared to $4.3 million under current practice.

The total data cost under the guidelines for new formulations (in addition to the testing on the active ingredients) would be $11,932 per product. This compares to $8,223 per product under current practice. The assumed 2,800 new formulations per year would result in a cost of $33.4 million under the guidelines as compared to $23 million under current practice. This would bring the total cost for data on new active ingredients and formulations under the guidelines to about $39.1 million per year compared with about $27.3 million per year under current practice.

VI. Costs of Guidelines Implementation Under Alternative Scenarios, 1980-89

A. Alternative Generic Standards Scenario Costs

Sales profiles, rates of return, and longevity of sales life will determine whether a registrant will make the decision to reregister any particular product. Appendix tables B-1, B-2, and B-3 provide a profile of active ingredients in registered insecticides, herbicides, and fungicides arranged by volume of sales from the largest to the smallest. The Agency assumes that the remaining types of pesticides, including disinfectants, would follow a similar pattern. In general, each class of products is dominated by a relatively few active ingredients when considered on the basis of sales. An important conclusion from this profile of sales it that there are many small volume active ingredients with production and sales which are so low that sufficient profit to support the additional costs imposed by reregistration under either current practice or the guidelines would be unlikely.

The timing of the imposition of the guidelines would affect the impact on the pesticides industry. The guidelines would be applied to presently-registered products at reregistration as part of the standards program. Under this plan, each currently registered product would retain its registration until such time as a generic standard has been established for the active ingredient(s) contained in the product. This analysis will include two scenarios by which reregistration could be accomplished using a generic standard setting approach:

Scenario No. 1. Fifty generic standards would be issued per year. As each standard is issued, the registrants of the products containing the active ingredient(s) covered by the standard would be informed of the additional data required to complete reregistration. EPA would then allow the registrant time to generate the needed data.

Scenario No. 2. Scenario No. 2 would be the same as scenario No. 1, except that each year registrants of products containing 100 active ingredients are notified of data deficiencies for which testing or other data gathering should be started. This notification schedule would continue for a period of 5 years. After 5 years, notification would fall back to 50 chemicals per year as under scenario No. 1. The early notification program is intended to reduce the time between the issuance of standard and final reregistration decisions. In effect, EPA would direct registrants to gather data on chemicals prior to developing the standards for those chemicals so that data needed to complete the standard are available at the time or shortly after the standard is issued.

Scenario No. 2 was selected as representative of many possible scenarios which have an early notification feature. For example, if early notification were given to all chemicals having agricultural or food crop uses in the first year of the reregistration process, the costs would be extremely bunched in the early years of the scenario. The overall costs depend on the number of chemicals reviewed. For scenario No. 2 and other similar possible scenarios, the total costs over all years would be the same, but the annual costs would vary depending on the schedule of review for the chemicals.

The order in which pesticides are selected for the generic standards program would also affect the impact of the guidelines. The approach to be taken by the Agency in either scenario No. 1 or scenario No. 2 is to select first the high-volume pesticides with emphasis on those pesticides applied to agricultural and food sites. These pesticides generally would require more extensive data in the areas of human hazard and environmental chemistry testing because of level and kind of exposure potential of such use patterns. The Agency would then proceed to establish standards on those chemicals which generally would require lower levels of expenditures for data.

Table 17 provides estimates of the total cost of data to be required annually under scenario No. 1 for both current practice and the guidelines. As described previously, 50 standards would be established each year for a period of 10 years and beyond. Following the establishment of the standards, industry would have to decide whether to conduct the testing required to obtain the data necessary for reregistration. As standards are issued year after year, some products would be voluntarily canceled, particularly as the lowest sales volume products are reached. This would occur under both current practice and under the guidelines. The withdrawal rate is, however, lower under current practice because of the lower cost involved.

Table 17 also shows the annual expenditures per active ingredient committed to reregistration. (See appendix C for cost derivation.) It is assumed that the cost for an individual active ingredient will be incurred over a 4-year period. The estimated costs per active ingredient reflect the Agency's intention to develop standards first on those products requiring the greatest amounts of data. The estimated costs also recognize that some data already exists in Agency files which would meet both guidelines requirements and current practice requirements. The cost figures have also been adjusted to include the estimated additional expenditures needed to develop data on formulations containing the active ingredients for which generic standards have been established. Calculations derived from the cost analysis indicate that data for formulations would add approximately 25 percent to the data cost under current practice and 40 percent under the guidelines.

Table 18 provides the annual costs expected to be incurred under scenario No. 2 for both current practice and the guidelines. The cost estimates reflect the same assumptions as were made for table 17, except for the accelerated pace with which decisions are made on chemicals as a result of early notification.

Tables 17 and 18 provide estimates of the annual costs under scenario No. 1 and scenario No. 2, respectively, for a 10-year time period. Projections beyond this time become increasingly uncertain. However, projections of the total costs and impacts on the number of products remaining in production after completion of reregistration is of interest. Certain data are available which can, with the use of averages and proportions, be used to project the costs and impact on the number of products beyond the first 10 years of either scenario No. 1 or scenario No. 2.

Projections of the number of active ingredients represented by products to be reregistered, costs of current practice data requirements, guidelines requirements, incremental costs, value of acceptable data, and projected outlays for active ingredients actually projected to be reregistered are contained in table 19 for scenario No. 1 and scenario No. 2. All costs include costs for the formulated products as well as for the active ingredients.

It was useful to break down the total of 1,460 active ingredients contained in registered products into those which are currently in production and those which are not currently in production. After reviewing production figures reported to the Agency, an estimate was made that 1,000 active ingredients are currently in production, and the re-

maining 460 active ingredients are no longer produced. The assumption is made that these 460 active ingredients would not be reregistered.

Of the 1,000 active ingredients currently in production, line 1 in table 19 provides estimates from tables 17 and 18 of the number projected to be reregistered in the first 10 years of scenario No. 1 and scenario No. 2. The associated costs for these active ingredients are also included. The actual projected outlays are the difference between guidelines requirement costs and the value of acceptable costs which would have been incurred for the active ingredients not projected to be reregistered in the first 10 years of either scenario, if the data were to be generated. Since the active ingredients on line 2 are not projected to be reregistered, there is a zero entered for projected actual outlays on that line.

Line 3 is the summation of lines 1 and 2. Under scenario No. 1, in the first 10 years 395 out of 500 active ingredients would be reregistered with projected actual outlays of $322 million.

Of the 1,000 active ingredients assumed to be in current production, 500 and 250 active ingredients under scenario No. 1 and scenario No. 2 remain to be reviewed. One assumption that can be made is that one-half or 250 of the 500 active ingredients in scenario No. 1 would eventually be reregistered. To be consistent, 120 of 250 active ingredients remaining in scenario No. 2 would be likely to be reregistered. The total number of active ingredients reregistered would then be 645 out of 1,000 under either scenario. Line 4 shows the costs of data for all 500 and 250 active ingredients in the two respective scenarios, except that the projected actual outlays are calculated only for the 250 and 120 active ingredients projected to be reregistered.

Line 5 provides these subtotals for the costs of data for all 1,000 active ingredients currently in production. The projected actual outlays for the 645 active ingredients projected to be reregistered is $473 million and is included on line 5.

Line 6 provides estimates of the value of data which would be needed to support the reregistration of the 460 active ingredients not currently in production. Since for this analysis the assumption is made that these active ingrednents will not be reregistered, a zero is entered for projected actual outlays for this line.

In summary, of 1,460 active inngredients contained in registered products, 645 would be reregistered eventually. These 645 active ingredients represent about 95 percent of the volume of all pesticides produced in the United States based upon reported production. Eight hundred and fifteen active ingredients (400 of this total are not currently in production) representing about 5 percent of the volume of pesticides produced in the United States are not projected to be reregistered under the current market, regulatory, and legislative structures.

Line 7 provides the projections of the value of data for all 1,460 active ingredients contained in registered products. The current practice costs are about $690 million, and the guidelines costs are about $950 million. The value of data submitted and acceptable is about $150 million. After adjusting for active ingredients not projected to be reregistered, the projected actual outlays are $473 million or about 50 percent of the total cost of data under the guidelines.

B. COMPARATIVE COSTS OF ALTERNATIVE SCENARIOS.

Table 20 contains comparative annual costs of the guidelines for both reregistrations and new registrations under both scenario No. 1 and scenario No. 2 for reregistration. The time period 1980-89 is used because this period would cover most major pesticides for reregistration purposes. Projections beyond this time would embody a high degree of uncertainty, given the opportunities for changes in both the regulation of pesticides and in the pesticide market.

The current requirements and the incremental costs for a given pesticide product are the same under both scenario No. 1 and scenario No. 2. Therefore the costs on an annual basis for data in support of new registrations are equivalent in both secnarios.

The early notification feature of scenario No. 2 is expected to create higher outlays in the early years of the time period in comparison to scenario No. 1. In both scenarios, costs would rise to a peak in 1983 ($89 million under scenario No.1 and $118 million under scenario No. 2) before starting to decline.

Although the annual costs would differ significantly between the two scenarios, the differences are not spectacular. Costs would decline at a faster rate in scenario No. 2 after 1983; after 1985 the annual costs of scenario No. 2 will have fallen below the annual costs of scenario No. 1.

For each scenario, separate data are presented for incremental costs, for costs of meeting current requirements including data gaps and for the total—which corresponds to full implementation of the guidelines under the scenario. In the peak year of costs, 1983, incremental costs under scenario No. 1 would equal $29 million, or about one-third of the total of $89 million (compared with costs of $60 million to meet current requirements). A similar ratio would exist for scenario No. 2.

VII. ECONOMIC IMPACT ANALYSIS

A. PESTICIDE INDUSTRY IMPACTS

Profile of industry. Pesticide production (SIC Code 2879) is one component of the Chemicals and Allied Products Industry (SIC Code 28). Below are some statistical comparisons for the year 1977 which show the relative size of the pesticide producing industry compared to the chemical industry as a whole:

	Pesticides (SIC-2879)	Chemicals and allied products (SIC-28)
Value of shipments	[1]$2,900	[1]$112,000
Total employment	15,000	885,000
Production workers	9,000	555,000
Value added per production worker	[2]$75.92	$44.96

[1]In billions of dollars.
[2]Figure for 1975, 1977 data not available for pesticides.

SOURCE: U.S. Department of Commerce, 1978.

Pesticide production accounts for 2.6 percent of the chemical industry value of shipments and 1.7 percent of total employment. Pesticide industry production workers comprise only 1.6 percent of all chemical industry workers. Value added per production worker in the pesticide industry was almost 70 percent higher in 1975 than for the chemical industry.

Pesticides are considered to be speciality chemicals in the realm of chemical industry products. Many pesticides are protected by patents. This protection probably explains much of the greater value in output per production worker hour enjoyed by the pesticide producers in comparison to the whole chemical industry.

Pesticide production involves manufacturing of an active ingredient, usually in its manufacturing-use form, and then preparing formulated products containing the active ingredient. The firms which produce manufacturing-use products are a small number of the firms involved in pesticide production. Most firms which formulate pesticides do not also produce the manufacturing-use products.

A contract study for EPA (EPA, 1976) found that as few as 12 pesticides could account for more than 40 percent of the value of all pesticide sales. It was further estimated that the 10 largest producers account for 75 percent of U.S. pesticide production. Data from industry surveys (National Agricultural Chemicals Association 1970, 1974, 1977) indicate that as few as 7 firms account for 50 percent of pesticide industry R. & D. expenditures and 60 percent of production, and that fewer than 50 firms produce virtually 100 percent of the active in-

gredients in pesticides used by the agricultural sector.

Basic pesticide-producing firms are a small group. Two-thirds of these forms ar large chemical- or petroleum-producing firms (EPA, 1975). Several of the remaining firms are involved in pharmaceutical production. Firms in these three groups generally rely on pesticides for less than 20 percent of total sales. It is generally the smaller basic producer for which perticides comprise a majority of the dollar sales volume.

The above data indicated that the pesticide industry is highly concentrated or oligopolistic at the basic producer level, including R. & D. Actions of any of these large individual firms can significantly influence the pesticides. This situation is in contrast to the formulation sector of the industry, where much less concentration exists.

Firms that formulate pesticide products generally purchase the manufacturing-use products from the basic producers. Formulating firms cover a wide range of sizes. One study prepared for EPA (EPA, 1976) gave the following estimates as to the number of firms which formulate pesticides:

Category	*Estimated No.*
Large formulators	500
Medium-size formulators	1,000
Small formulators	1,848
Total [1]	3,348

[1] Not included are basic producers who also formulate pesticides.

COST IMPACTS AT BASIC PRODUCER LEVEL

The incremental cost impacts of the guidelines will initially be borne by the pesticide-producing industry, including both formulators and basic producers. The distribution of these costs among the types of firms in the industry and their significance will be discussed below. Table 21 presents annual incremental and total costs of the guidelines estimated for the two scenarios discussed above, in comparison with domestic sales value of pesticides and in comparison with pesticides R. & D. expenditures covering the period 1980-89. Domestic sales include domestic sales of domestic production and imports, but exclude export sales of domestic production (equal to approximately 30 percent of U.S. production). The projections for domestic pesticides sales value are based on sales of $2.035 billion for 1976 and a 4.0 percent annual growth rate, which is conservative, but in line with current projections (EPA, 1978; Farm Chemicals, 1977; Ouellette and King, 1976). The base year (1976) and all projections are standardized at the 1977 price level.

Total pesticide R. & D. expenditures are projected at a rate of 7.0 percent of the domestic sales value of pesticides. This rate is slightly lower than the 1970-76 average (7.6 percent) reported by NACA, but provides a conservative basis for comparing the incremental R. & D. costs of the guidelines (NACA, various years). The registration-related R. & D. expenditures are projected at a rate of 2.0 percent of domestic sales, equal to the 1970-76 average reported by NACA (NACA, various years). These registration-related R. & D. expenditures are approximately 30 percent of the total R. & D. expenditures.

In scenario No. 1, the incremental cost of the guidelines would equal 0.4 to 1.1 percent of projected domestic pesticide sales at the basic producer level, 6.3 to 15.5 percent of projected total R. & D., and 22.1 to 53.7 percent of projected registration-related R. & D. Including the data gaps (which must also be filled) will cause these percentages to approximately triple. The year of greatest impacts for all comparisons given is 1983.

In scenario No. 2, the incremental cost of the guidelines range from 0.4 to 1.4 percent of projected sales and 5.9 to 20.3 percent of projected registration-related R. & D. Including the data gaps, these percentages increase by three of four times, depending on the year. Whereas the cost impacts are rather minimal compared to projected sales (i.e., in the range of 0.4 to 4.4 percent, depending on the year and the scenario), they are substantial when compared to R. & D., total or registration-related. Clearly, implementation of the guidelines would have a large impact on pesticides R. & D. Total R. & D. could be required to increase by about one-half, and registration-related R. & D. could be required to double or triple temporarily, as costs peak out during 1981-85.

Under both scenarios, the greatest percentage impacts would occur in 1983 and trend downward after that year. The decline would likely be caused primarily by two factors:

1. The large volume agricultural/food active ingredients would be reregistered first and they require the largest data cost outlays;

2. Some small sales volume active ingredients are not expected to be reregistered.

The projected annual cost from implementing the guidelines presented above are likely to be translated into price increases for sales of pesticides at the basic producer level of the industry. The magnitudes of such price increases are likely to be within the range of 2 to 3 percent on industry sales on an average during the 1980's. The rationale for this is as follows:

1. The demand structure for pesticides is generally assumed to be price inelastic (EPA, February 1978, page 16). This means that purchasers of pesticides tend to maintain the quantity of pesticides purchased in the face of price increases, e.g., a 1.0 percent increase in price generates less than a 1.0 percent reduction in the quantity clearing the market.

2. The guidelines would be imposed on an industry wide basis with a schedule bringing similar types of uses under the guidelines during the same period. Competing pesticide products for agricultural/food uses would generally be brought under the guidelines requirements by a generic standard approximately the same time. The probability of price increases is greater in this instance because competing products would tend to experience the cost increases during the same general time frame. In the process, the tendency would be to minimize impacts on competitive relationships among products used on the same sites.

3. There are no data to indicate that price increases would exceed the cost impacts of the guidelines through add-ons markups. Likewise, there are no data indicating that the industry would absorb these costs.

4. Costs would be passed on in the form of price increases during the approximate time frame during which the costs were incurred. There is no basis for projecting price increases substantially in advance of increased costs or for projecting that price increases would be continued after costs had peaked out and have begun to decline.

The above discussion only addresses average price increases at the basic producer level. Effects on individual formulated products or active ingredients might vary considerably. For many products, no doubt, data gaps would be small. The industry may have anticipated requirements for other products, and thus may already have incurred most of the costs of meeting guidelines requirements. In those instances, the additional cost would be minimal and a firm would not feel the need to increase prices.

In other cases, large data gaps would exist which would stimulate above-average price increases. The cost of the guidelines for small volume active ingredients could be substantially above average, e.g., in the range of five to ten percent increases. In some instances these costs could be sufficiently high so that prices could not be raised to cover the cost. In such cases, products containing those active ingredients would no longer be produced. The matter of loss of products associated with active ingredients not submitted for reregistration is discussed below.

The reregistration of existing pesticides under either current practice or the guidelines would require a decision

by the registrants as to whether the additional data expense is justified given the profitability and expected future sales of their pesticides. As previously stated, there are approximately 1,460 active ingredients identified in the currently registered products. Several of these active ingredients will likely become uneconomical under either reregistration scenario and under both current practice and the guidelines.

A review of current registration containing pesticidal active ingredients indicates that about 460 of the 1,460 active ingredients are not currently being produced. Applications for many of the products containing these active ingredients probably would not be submitted for registration. Of the active ingredients which are produced, many are produced in relatively very low volumes. To estimate the proportion of active ingredients which might become uneconomical to produce under current market conditions, a review of production levels was compared to the estimates of data cost. (See appendix C). Tables 17 and 18 include estimates of the number of active ingredients which would be expected to be withdrawn during reregistration under scenario No. 1 and scenario No. 2, respectively. As is indicated, most of these active ingredients would likely become uneconomical under both current practice and the guidelines.

In scenario No. 1, 80 out of 500 active ingredients are estimated to be withdrawn under current practice as compared to 105 out of 500 if the guidelines are implemented. In scenarios No. 2, 190 out of 750 active ingredients are projected to be withdrawn under current practice as compared to 225 out of 750 under the guidelines. On an incremental basis, the numbers of active ingredients withdrawn are 25 and 35 under scenario No. 1 and scenario No. 2, respectively.

The estimates of the number of active ingredients which might be withdrawn are not precise, but the error would tend to overstate the withdrawal rate of active ingredients which are now being produced. Several factors could reduce the cost of data and/or improve the market outlook for any one active ingredient which on first review would appear to be uneconomical. The previously discussed provisions for waviers would provide the greatest area of relief in terms of reducing data costs. For those costs which must be incurred, the market for individual chemicals might permit comparatively large price increases which would fund the required testing costs. In effect, for chemicals providing high benefit-to-cost ratios for users, the users would provide the funding for testing indirectly. User groups also directly fund testing in cooperation with pesticide manufacturers. The combined welfare of producers and users of pesticides might be greater than the cost of providing needed data. It would therefore be to their mutual advantage to fund the testing either directly or indirectly.

Scenarios No. 1 and No. 2 would bring the major sales volume pesticides under new proposed guidelines requirements within two or three years. At a rate of 50 generic standards per year, the top 125 active ingredients, which account for three-fourths of industry production of insecticides, herbicides and fungicides (see appendix B), would be brought under the new requirements of the third year under scenario No. 1, and needed data would be generated during the three or four years following issuance of the standards. This rate is accelerated under scenario No. 2. Within 5 to 10 years, 200 pesticide active ingredients accounting for about 90 percent (by volume) of all pesticides produced would be reregistered or conditionally reregistered.

The impacts on major products are projected to be slight for two prime reasons:

1. The costs imposed by the guidelines are small relative to annual sales. The one-time cost imposed by the guidelines, including filling data gaps, for a major agricultural pesticide is about $1 million. This is less than 2 percent of sales over a 4 year period during which requirements would be met ($1.0 million as percent of 4 years sales at $15 million per year; see appendixes B and C).

2. Many of the costs of the data requirements of the guidelines have already been met for the typical major agricultural/food pesticides, due to the "defensive research" that has been the increasing practice of may firms during recent years (EPA, 1978). About one third of the costs are estimated to have already been incurred for a typical major agricultural pesticide active ingredient (appendix C), which reduces the one-time cost to near $600,000 or about 1 percent of sales over a 4-year period.

Impacts on Formulated Products. Formulated products have data requirements in addition to the data requirements on the active ingredients contained in the products. This section is intended to provide a sales profile for formulated products which can be compared to estimates of the cost of data needed on formulations during reregistration.

As presented earlier in this analysis, there are approximately 33,750 formulated products which have EPA registrations. On the basis of the pounds of active ingredients used to produce the formulations, production estimates range in size from less than 10 pounds to several hundred thousand pounds. A random sample of 20 active ingredients representing 1,343 registered formulated products was reviewed and the pounds of active ingredients used to produce the products in 1975 were then arrayed. Table 22 summarizes the array which indicates that, in similar fashion to the active ingredients, the production of formulated products has a skewed distribution. For example, about 5,000 or 16 percent of the products are formulations of more than 20,000 pounds of active ingredients whereas 21,000 or 67 percent of the formulation are formulated from 5,000 pounds active ingredients or less.

TABLE 22.—*Estimated sales value and number of EPA registered formulated products, by production volume category, 1977, based on a sample of 1,343 products*

Pounds active ingredient	Sales value[1]	Products	
		Percent of total	Number
Zero or no report	0	8.2	2,624
1 to 5,000 lbs	$4 to $20,000	58.7	18,784
5,000 to 10,000 lbs	$20,000 to $40,000	9.2	2,944
10,000 to 20,000 lbs	$40,000 to $80,000	8.2	2,624
More than 20,000 lbs	More than $80,000	15.7	5,024
		100.0	32,000

[1] Current estimated pesticide sales at user level is approximately 1.2 billion lbs with a value of $5 billion. This gives an approximate average of $4 per pound of active ingredient for formulated products at the user level.

The value of formulation on the basis of dollars per pound of active ingredient contained in the formulations is highly variable. Generally, specialty

pesticides which might be sold for home and garden use would have higher prices per pound of active ingredient than pesticides intended for use in agricultural crop production. Currently approximately 1.2 billion pounds of pesticides are produced on an active ingredient basis. The retail value is estimated to be about $5 billion. This is an approximate average $4 per pound of active ingredient. This figure can be used to convert the pounds of active ingredient contained in formulations to retail value. Table 22 uses the $4/pound active ingredient estimate to complete the profile of formulated products.

The data cost to be borne by pesticide formulators is also variable, but some generalizations can be made to focus on the impacts of the guidelines requirements of formulations. Table 16 showed that for an average new formulation, the cost of tests or submissions of data in which the formulated product is involved equalled about $8,000 under current practice and $12,000 under the guidelines. The average cost for reregistering formulated products is approximately the same, since little acceptable data are currently in EPA registration files. The average costs are not indicative of the costs to be incurred for a typical formulation during reregistration because the costs are skewed, i.e., a very few formulated products will require the relatively large cost outlays for data.

Table 23 provides the costs of data that would be incurred by formulators which would be sufficient for 90 percent of the formulated products to meet the requirements for both current practice and the guidelines. These data are extracted from tables 1, 3, 4, 6, 7, 9, 11, 12, and 14. Thus, if no waivers were available, 90 percent of the registered pesticide formulations would be faced with potential costs of $5,100 or $8,900 per product under current practice and the guidelines respectively.

Comparison of the data required for typical formulations with the profile of production and sales suggested that some products would be adversely impacted unless special handling were provided by the Agency to reduce costs.

The formulated product survival rate cannot be determined by a simple comparison of the data cost under the guidelines with the current level of sales, since data sharing and waivers would lower the costs to be incurred for many formulations.

TABLE 23.—*Cost of data sufficient to meet requirements for 90 pct of formulated products for reregistration*

Guidelines subject	Current practice lines	Guide-
Product chemistry	$2,050	$4,300
Environmental chemistry	0	0
Special chemistry	0	0
Fish and wildlife hazard	0	0
Human hazard	3,050	4,500
Total	5,100	8,900

Source: These figures are extracted from tables 1, 3, 4, 6, 7, 9, 11, 12, and 13.

Sales figures could also change if market conditions permit the formulators to raise prices. Formulated products with specialized uses would be candidates to increase prices in order to generate sufficient revenues to cover the additional data costs imposed during reregistration.

Sales of some products would likely increase when competing products are withdrawn. In effect, the market of a particular active ingredient would change to reflect the withdrawal of a competing formulated product.

In conclusion, pesticides representing 90 percent or more of the current level of production should still be available after a 5 or 10 year period under any likely reregistration scenario. The guidelines requirements in themselves do not create the loss of the pesticides representing the remaining 10 percent of pesticide production. Some of the pesticides espected to be withdrawn would likely be withdrawn under current practice also. The attrition rate will probably be higher under the guidelines than under current practice.

The range of formulated products made from each active ingredient is likely to be reduced. The surviving products should fill the demand then created. The cost of testing to support formulated products would not be expected to adversely impact the availability of active ingredients.

Competitive impacts. The pesticide industry at the basic producer level is highly concentrated (oligopolistic), i.e., a few individual firms have significant shares of the various pesticide markets. These market shares allow the firms to assert themselves by influencing price, quality, and quantity of pesticides available. Market power, such as that of basic producers of pesticides, generally comes about because of barriers to entry into the market faced by other firms. Barriers to entry include such factors as patent protection and large initial investment. The basic pesticide producing industry is affected by both of these factors.

A market survey done for EPA by Doane Agricultural Service showed that, for many major crops, 8 or fewer insecticides and 8 or fewer herbicides would account for 75 percent of the respective markets (Doane, 1975). In some crops such as corn, cotton, and soybeans, 4 insecticides could account for up to 75 percent of the insecticide market for those crops depending on pest infestations. Competition in the market is further reduced when one considers that in each market there are geographical differences. The markets are even more concentrated at the state level than at the national level.

Any decisions by basic producers to withdraw their products from the market would tend to further increase the degree of concentration. Since products representing 90 percent of the total sales volume of active ingredients are expected to be reregistered, market disruptions at the basic producer level are unlikely.

Some low volume pesticides would likely be withdrawn from the market. The loss of these small volume active ingredients, many of which are not in current production, is of some, but limited, significance with regard to competition in the current market for pesticides. Their loss would improve the competitive position of the major products which already account for most of the market in the large scale uses. The small volume products often, however, are major factors in many minor uses of pesticides. The chief significance of the loss of such products and the increased cost of the guidelines implementation may well be on future competition.

The guidelines have the effect of increasing requirements to enter market, i.e., increasing barriers to entry, a factor which affects the potential competition in the industry. Because new product success is closely associated with R. & D. efforts, and because guidelines have the effect of increasing R. & D. costs for new products, the guidelines will affect entry into the industry to some extent. R. & D. already is quite concentrated at the present time, as discussed above (7 firms account for 50 percent of industry R. & D. and more than 60 percent of sales), and is at a rate about twice that for U.S. industry on the average (more than 7 percent on sales, compared with about 3.5 percent for all industry) (EPA, 1978). This is particularly significant at a time when firms are looking more toward expanding the use of existing active ingredients rather than developing new ones about which less would be known (from environmental and human health standpoints).

The impacts of the guidelines upon formulators would be minimized because they would be phased over a period of 10 or more years. This would permit formulators to adjust to prod-

uct losses over an extended period. However, there is a component of the formulating industry which consists of firms which often formulate only one product as a sideline to other businesses. Many such firms may go out of the pesticide business if they must pay full or even partial costs of meeting data requirements of the guidelines. The loss of such small scale formulator operations would not be of great significance to the industry or to the pesticide users.

Competitive relationships between basic producers and formulators would remain largely unaffected by the guidelines, aside from the matter of cost sharing, which takes on added significance due to the larger expenditures involved. The potential for joint ventures of producers and formulators in R. & D. pesticides might increase because of the increased R. & D. expenditures on new products.

B. PESTICIDE USER IMPACTS

The purpose of this section is to indicate the nature and extent of the impacts of the guidelines on pesticide user sectors, such as agriculture, industry, commerce, government, home and garden. Indirect impacts on the consumer of products or services which involve pesticides as an input are considered later in this report.

The direct user of pesticies could be affected in two ways by implementation of the guidelines:

1. Potentially increased prices of pesticides, as some or all of the additional costs of the guidelines are passed on through the marketing system, and
2. Potential unavailability of specific active ingredients and formulations of pesticides, should they no longer be profitable to produce.

The potential for pesticde price increases due to the incremental and total costs of the guidelines is addressed by translating the costs of the two scenarios into user impacts by assuming that those costs are passed on completely to the user, i.e., none are absorbed by producers and formulators and there are no add-ons or markups. These are probably reasonable assumptions on the average, for purposes of approximating actual impacts.

These user impacts were compared with projected user expenditures for pesticides on an annual basis for the period 1980-89. The projections were obtained by assuming an annual growth rate of 4.0 percent from a base of $4.5 billion for the year 1977. This rate of growth is somewhat conservative compared to the 6 to 8 percent rate predicted by Christodouhi (Farm Chemicals, 1977) or the 5 percent annual rate for tonnage predicted by Ouellette and King (Ouellette and King, 1976), but is not unreasonable for projections in real (constant dollar) terms. All projections of user expenditures and costs of the scenarios are expressed in terms of the 1977 price level. The result of this projection is pesticide user expenditures of about $5.06 billion in 1980, which trend upward to $7.20 billion in 1989 (table 24).

For all users of pesticides, the incremental costs of the guidelines under scenario No. 1 would be equal to 0.3 to 0.5 percent of projected baseline pesticide user expenditures during the 1980's through 1985 (up to 1.6 percent if data gaps are included). They decline moderately by the end of the 1980's. For scenario No. 2, the user impacts peak out in 1983 at 0.7 percent for incremental costs and 2.1 percent for total costs, compared to expenditures projected according to normal trend. These impacts are small but are occurring over an extended period and reflect only industry averages. Prices paid by some users would be impacted much more than others. The figures in table 24 are only approximate averages assuming straight passthrough of costs.

User impacts were evaluated for the two scenarios described earlier in this report. For scenario No. 1, the total costs (incremental plus cost of filling data gaps) over the 10-year period were projected to be $712 million, equal to 1.2 percent of the total user expenditures of $60.8 billion (table 25). For scenario No. 2, these costs ($765 million) equal 1.3 percent of user expenditures. The incremental costs of $220 million and $234 million for scenarios No. 1 and No. 2, respectively, equal 0.4 percent of user expenditures.

The distributional aspects of these impacts were addressed by separating the users into three market sectors: Agriculture, industrial/commercial/governmental, and home and garden, and projecting both expenditures and impacts by sector. User expenditures were distributed among the sectors according to the findings of a study (EPA, 1974) that estimated the sector breakdown as agriculture, 63 percent; industrial/commercial/government, 25 percent; and home and garden, 12 percent. This distribution was centrally located among the range of distribution reported by USDA and Farm Chemicals.

The above costs of the guidelines averaging 1.3 percent on projected user expenditures of pesticides can be projected as indications of the extent to which price increases would be likely to occur at the user level of the industry during the 1980's. On the average, the same general rationale applies to price increases at the user level as for the basic producer level discussed in an earlier section of this report (see section entitled "Cost Impacts at Basic Producer Level"). Though the price impacts may vary from product to product, the above averages are reasonable approximations of price increases. To users, on the average, these price impacts will also vary by sector of the economy.

Most all categories of users would be affected to some extent because the guidelines would affect active ingredients with formulations in all sectors. However, the agricultural sector was assumed to be impacted more heavily at first since the active ingredients used in agricultural pesticides are to be given priority in reregistration.

The cost impacts by sectors are presented in table 25 for both scenarios No. 1 and No. 2, for the 1980-89 time period. These impacts are weighted more heavily toward the agricultural sector early in the time period until the 350 active ingredients used in agricultural pesticides will have presumably been evaluated. For scenario No. 1, this takes 10 years, so the bias toward the agricultural sector lasts throughout the full 10-year period. The annual costs were distributed using the following proportions: Agricultural, 75 percent; industrial/commercial/governmental, 15 percent; home and garden, 10 percent.

Table 24

Comparison of Projected Annual Cost of Meeting Guidelines Requirements with Expenditures of Domestic Users for Pesticides, 1980-89 Projections, by Alternative Registration Scenarios

Expenditures, Costs and Comparison	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989
Pesticide users expenditures[1/] ($ million)	$5,062	$5,264	$5,475	$5,694	$5,922	$6,159	$6,405	$6,661	$6,927	$7,204
Costs of Scenario #1										
Incremental only										
Cost ($ million)	$ 17	$ 23	$ 26	$ 29	$ 26	$ 25	$ 23	$ 18	$ 18	$ 15
Compared to expenditures	0.3%	0.4%	0.5%	0.5%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%
Including data gaps										
Cost ($ million)	$ 53	$ 68	$ 79	$ 89	$ 84	$ 81	$ 73	$ 65	$ 63	$ 57
Compared to user exp.	1.0%	1,3%	1.4%	1.6%	1.4%	1.3%	1.1%	1.0%	0.9%	0.8%
Costs of Scenario #2										
Incremental only										
Cost ($ million)	$ 22	$ 29	$ 36	$ 38	$ 29	$ 23	$ 15	$ 14	$ 14	$ 14
Compared to exp. (%)	0.4%	0.6%	0.7%	0.7%	0.5%	0.4%	0.2%	0.2%	0.2%	0.2%
Including data gaps										
Cost ($ million)	$ 67	$ 89	$ 108	$ 118	$ 98	$ 78	$ 60	$ 52	$ 48	$ 47
Compared to exp. (%)	1.3%	1.7%	2.0%	2.1%	1.7%	1.2%	0.9%	0.8%	0.7%	0.7%

1/ Increases at a projected annual rate of 4% over base of $4.5 billion in 1977.

Table 25

Comparison Of Cost Impacts of Meeting the Guidelines with Domestic User Expenditures, Total and 1980-1989[1/]

Expenditures, Costs and Sector Categories	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	Sum	Comparison with Sector User Expenditures %
	$ million											
User Expenditures[1/]												
Total	5,062.0	5,264.0	5,475.0	5,694.0	5,922.0	6,159.0	6,405.0	6,661.0	6,927.0	7,204.0	60,773.0	
Agriculture	3,189.0	3,316.0	3,449.0	3,587.0	3,731.0	3,880.0	4,035.0	4,196.0	4,364.0	4,539.0	38,286.0	
Ind/Comm/Gov	1,266.0	1,316.0	1,369.0	1,424.0	1,480.0	1,540.0	1,601.0	1,665.0	1,732.0	1,801.0	15,194.0	
Home & Garden	607.0	632.0	657.0	683.0	711.0	739.0	769.0	799.0	831.0	864.0	7,292.0	
Scenario #1[3/]												
Incremental Costs	17.0	23.0	26.0	29.0	26.0	25.0	23.0	18.0	18.0	15.0	220.0	0.4
Agriculture	12.8	17.2	19.5	21.8	19.5	18.8	17.2	13.5	13.5	11.2	165.0	0.4
Ind/Comm/Gov	2.6	3.4	3.9	4.4	3.9	3.8	3.4	2.7	2.7	2.2	33.0	0.2
Home & Garden	1.7	2.3	2.6	2.9	2.6	2.5	2.3	1.8	1.8	1.5	22.0	0.3
Total Costs	53.0	68.0	79.0	89.0	84.0	81.0	73.0	65.0	63.0	57.0	712.0	1.2
Agriculture	39.8	51.0	59.2	66.8	63.0	60.8	54.8	48.8	47.2	42.8	534.2	1.4
Ind/Comm/Gov	8.0	10.2	11.8	13.4	12.6	12.2	11.0	9.8	9.4	8.6	107.0	0.7
Home & Garden	5.3	6.8	7.9	8.9	8.4	8.1	7.3	6.5	6.3	5.7	71.2	1.0
Scenario #2[4/]												
Incremental Costs	22.0	29.0	36.0	38.0	29.0	23.0	15.0	14.0	14.0	14.0	234.0	0.4
Agriculture	16.5	21.8	27.0	28.5	21.8	11.5	7.5	7.0	7.0	7.0	155.6	0.4
Ind/Comm/Gov	3.3	4.4	5.4	5.7	4.4	6.9	4.5	4.2	4.2	4.2	47.2	0.3
Home & Garden	2.2	2.9	8.6	3.8	2.9	4.6	3.0	2.8	2.8	2.8	31.4	0.4
Total Costs	67.0	89.0	108.0	118.0	98.0	78.0	60.0	52.0	48.0	47.0	765.0	1.3
Agriculture	50.2	66.8	81.0	88.5	73.5	39.0	30.0	26.0	24.0	23.5	502.5	1.3
Ind/Comm/Gov	10.0	13.4	16.2	17.7	14.7	23.4	18.0	15.6	14.4	14.1	157.5	1.0
Home & Garden	6.7	8.9	10.8	11.8	9.8	15.6	12.0	10.4	9.6	9.4	105.0	1.4

1/ 1977 price level.

2/ Total user expenditures increase at an annual rate of 4 percent over a base of $4.5 billion in 1977. Market sector distribution of user expenditures is the following: Agriculture - 63%, Industrial/Commerce/Government - 25%, Home and Garden: - 12%.

3/ Impacts are weighted to reflect greater focus on agricultural pesticides until the 350 tolerance chemicals have been evaluated. Market sector distribution is the following: Agriculture - 75%, Industrial/Commerce/Government - 15%, Home and Garden - 10%.

4/ Impacts are weighted to reflect greater focus on agricultural pesticides until the 350 tolerance chemicals have been evaluated - 5 yrs. After the focus is assumed to shift away from primarily agricultural chemicals. Market sector distribution is the following: first 5 years: Agricultural Industrial/Commerce/Government - 15%, Home and Garden - 10%, second 5 years: Agriculture - 50%, Industrial/Commerce/Government - 30%, Home and Garden - 20%.

Both this distribution and the one described below for scenario No. 2 are believed to be reasonable under the current program assumptions about implementing the guidelines. However, it must be recognized that the actual sector impacts can better be predicted after the specific sequence of active ingredients is established. For scenario No. 2, the impacts of the 350 food and feed crop use chemicals would be felt during the first 5 years, after which it is assumed that the impacts would shift away from agriculture and toward the other sectors. Accordingly, the annual costs were distributed among the sectors in the same proportion as scenario No. 1 for the first 5 years, i.e., agricultural, 75 percent; industrial/commercial/governmental, 15 percent; and home and garden, 10 percent, and in the following proportions for the second 5 years: Agricultural, 50 percent; industrial/commercial/governmental, 30 percent; and home and garden, 20 percent.

For agricultural users, the projected cost impacts of the guidelines represent a slight increase in overall production expenditures which total $87 billion in 1977. Pesticide expenditures account for less than 5 percent of production expenses in agriculture (3.8 percent in 1977). It is assumed that this relationship would remain fairly stable in the future. The total cost of guidelines implementation for pesticides used in the agricultural sector over the 10-year period are $534 million for scenario No. 1 and $502 million for scenario No. 2. On an average year basis, the total costs of the guidelines implementation are 0.6 percent of 1977 production expenses in the agricultural sector. If only the incremental costs are considered, the cost of the guidelines implementation are reduced to 0.2 percent of the 1977 production expenses.

Compared to the agricultural sector's pesticide expenditures, the guidelines implementation costs are 0.4 percent for the incremental costs and 1.2 to 1.3 percent for the total costs for both scenarios (table 25).

Data from various pesticide surveys indicate that as few as one-third or about 1,000,000 farms account for over 90 percent of farmer's expenditures on pesticides. Thus, the total impact of the guidelines implementation on one of these pesticide-using farms would average $48.06 per year for senario No. 1 and $45.23 for scenario No. 2. When only the incremental costs are considered, the per-farm annual costs are $14.85 for scenario No. 1 and $14 for scenario No. 2.

For pesticide users in the industrial, commercial, and governmental sectors, total cost impacts average $10.7 million per year during the 1980's ($15.8 million for scenario No. 2) which are quite insignificant in relation to the scope of economic activity involved (as much as three-fourths of the U.S. economy). If only the incremental costs are considered, the average annual cost impacts are $3.3 million for scenario No. 1 and $4.7 million for scenario No. 2. The projected 10-year pesticide expenditures for the industrial/commercial/governmental sector is $15.194 billion. The total guidelines impacts of $107 million and $158 million for scenarios No. 1 and No. 2 are equal to 0.7 and 1 percent of the sector pesticide expenditures, respectively. The incremental cost impacts are less significant, representing 0.2-0.3 percent of the sector expenditures.

For home and garden users of pesticides, annual total cost impact of implementing the guidelines averaging $7.1 million for scenario No. 1 ($10.5 million for No. 2) would not appear to be highly significant or burdensome. This cost would equal $0.03-$0.05 per capita or $0.07-$0.10 per household, assuming there are 100 million households in the United States.

Compared with home and garden sector pesticide expenditures of $7.29 billion, the total cost impacts are relatively small at 1 percent ($71.2 million) for scenario No. 1 and 1.4 percent ($105 million) for scenario No. 2. The incremental cost impacts are smaller yet, at 0.3 percent of sector expenditures for scenario No. 1 and 0.4 percent for scenario No. 2.

In summary, the sector impact of guidelines implementation on individual sectors is quite small, averaging 0.2 percent to 1.4 percent of sector expenditures.

As noted at the beginning of this section, in addition to increased costs, pesticide users could be affected by the loss of some low sales volume pesticide active ingredients and formulations following the implementation of the guidelines. Lack of sufficient registered products is already a significant problem, particularly for certain minor uses in agriculture, and a rapid implementation schedule for the guidelines could add to this problem. This matter is addressed in the sections to follow.

C. IMPACT ON SMALL VOLUME ACTIVE INGREDIENTS

The analysis of the impacts of the guidelines applied under reregistration scenarios indicates that the market for certain active ingredients would not justify the expense of generating the required data. A review of the guidelines requirements indicates that for most active ingredients, a minimum of $200,000-$250,000 in added data costs would be needed to obtain reregistration. For active ingredients requiring $250,000 in additional data, cash flow analysis indicates that sales of $232,000 per year for 15 years and a profit rate of 15 percent before taxes on sales would be required just to break even on the added expenditure when a discount rate of 11 percent is applied. It is apparent that firms would have to generate more than a break-even level of sales on their pesticide. A minimum of $500,000 in annual sales of an active ingredient would seem to be required. This level of sales would be the equivalent of 200,000-300,000 pounds of production on an annual basis.

A review of the production of active ingredients in registered formulated products indicates that approximately 460 of the 1,460 active ingredients are not currently produced. Another approximately 640 active ingredients are produced, but at a level or 200,000 pounds or below. The remaining 360 active ingredients have reported production greater than 200,000 pounds annually. (These production figures are for 1 year, 1975, but a comparison to intended production for 1976 showed no significant changes.) Therefore, a strict application of the guidelines for reregistration with current market conditions could make as many as 1,100 active ingredients uneconomical to produce. It should be pointed out that a strict application of current practice to reregistration would also make many active ingredients uneconomical. The number of active ingredients adversely impacted is estimated to be 10-20 percent lower under current practice as compared to the guidelines (900-1,000 active ingredients).

A preliminary analysis of 1,100 active ingredients in registered formulated products indicates that only about one-third had production volume of more than 250,000 pounds on an active ingredient basis in 1975. A 10-percent screening of the remaining small volume registrations (about 800 of them) indicates that 20 to 30 percent do not have close alternatives in the large volume category above 250,000 pounds (active ingredient basis). Although this analysis is very tentative, it indicates that there are a number of small volume registered chemicals which do not have large volume alternatives.

The impacts on small volume active ingredients could be reduced by waivers of requirements for certain chemicals as provided for in the proposed guidelines. Waivers can be granted when sufficient data are available to allow a finding that a pesticide will not cause unreasonable adverse effects on the environment. Thus for many pesticide active ingredients, their limited use patterns and hence possible limited exposure risk could significantly reduce the quantity, type, and

hence the cost of data needed for reregistration.

Presently the Senate and the House of Representatives are considering identical amendments to FIFRA requiring of the Administrator of EPA: "* * * in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the extent of use, pattern of use, and level and degree of potential exposure of man and the environment to the pesticide. In development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data."

The proposed amendment applies to minor use and has implications for small volume active ingredients. It can be expected that if the generic standards procedure for registration is implemented, special consideration will be given to data requirements on many small volume active ingredients to lessen the cost burden. The number of active ingredients which would then remain economic to reregister and produce cannot, however, be estimated.

D. MINOR USE IMPACTS

A minor use of a pesticide is a relative term relating to the volume of a pesticide applied to a site. Minor use can, for example, encompass a small sales volume active ingredient applied to a few sites. Commonly, minor uses involve major sales volume pesticides which have major applications such as on corn or cotton. A minor use of a pesticide, thus, is any use which accounts for only a small proportion of the total pesticide's use.

Minor use problem areas have been identified for several years. A program known as Interregional Research Project 4 (IR-4) was established by USDA in 1963 which, in cooperation with State experiment stations, produces data to support minor use registration. Data requirements at that time were much less costly than under current practice or the guidelines. A problem for minor uses exists whenever the use of the pesticide desired (either large sales volume or small sales volume) has market potential too small to justify taking the steps necessary to make the product available for that use. Implementing the registration guidelines, which have been identified as increasing costs, can contribute to minor use problems.

The impact of implementation of the guidelines on the minor use problem is indirect. The guidelines in themselves do not impose specific requirements for minor uses. In fact, the data generated in support of the registration of a major use may be cited to support the registration of a minor use. The guidelines contained in subparts B, D, E, and F, if implemented, would impact on the minor use problem largely to the extent that it is not economical to conduct the required testing for every use.

As has been discussed, pending amendments to FIFRA require the Administrator to give special consideration to scale data requirements (the guidelines included) to accommodate minor uses. This does not mean that the minor use problem would be completely solved. It would only tend to minimize such impacts. Market conditions and product liability will still combine to create minor use problems.

E. EMPLOYMENT AND PLANT CLOSURES

This section examines the impacts of the guidelines on employment and plant closures. The projected dislocations are presented along with adjustments expected in a dynamic industry such as pesticides.

U.S. Department of Commerce (1978) estimated that total employment in the sector "Agricultural Chemicals Not Elsewhere Classified" (pesticides) was 15,000 in 1977. Of this total employment, 9,000 were production workers. These employment figures are probably somewhat understated. Pesticide formulation, for many small and large firms alike, is only a portion of their business. the workers would generally spend only a portion of their time in formulating pesticides, and therefore may not be considered as fully employed in the manufacture of pesticide formulations.

The establishments which are identified as primarily producers of pesticide formulations (SIC Code: 2879) number 388 according to U.S. Department of Commerce (1978). EPA lists 5,300 plants manufacturing pesticide formulations. The large discrepancy appears to be due to two main factors. First, EPA records carry plants which produced pesticide products in the past, but no longer do so. Second, pesticide formulation occurs at plants or establishments which are primarily in other lines of checmical product manufacturing, and therefore would fall under other SIC Code numbers.

This analysis has made the projection that under two possible reregistration scenarios under the guidelines, pesticide products containing 645 active ingredients would be reregistered over a period of 10 years and beyond. These 645 active ingredients represent about 95 percent of the current volume of pesticides produced. It is therefore possible that workers involved in the production of products containing the residual 5 percent of active ingredients may lose their positions. For the 15,000 workers at establishments whose primary output is pesticides, a 5-percent dislocation of jobs would equal 750 persons who might be displaced. These displacements would take place over a 10-20-year period or at an average rate of 38-75 positions per year.

Under current practice, projections were made that products containing an additional 50-75 active ingredients would be reregistered. These additional active ingredients represent only about 1 percent of current pesticide production. Therefore, using the same assumptions as above, the employment impact of reregistration under current practice might lead to a dislocation of 4 percent of 15,000 jobs or 600 persons over a 10-20 year period. On an annual basis, 30-60 jobs might be adversely affected. The incremental impact on employment dislocation under the guidelines as compared to current practice would be 8-15 jobs per year or a total of 150. These conclusions are derived from averages which are then applied to an industry structure which varies from small one person operations to large multimillion dollar chemical production facilities. The fine detail may vary, but the overall conclusions should be in the correct range of impacts.

To a large degree, the employment effects would be offset since the pesticides projected to be reregistered (or additional new products) can be expected to substitute for products withdrawn from registration. Distributional effects might occur however as jobs at predominately small firms are lost while jobs at larger firms are likely to increase. There is no logical reason to believe that the jobs shifts would be contained in the same geographic areas. Workers in small geographically isolated pesticide manufacturing firms might need to seek other lines of employment in their geographic area. The pesticide industry is a growth industry, with sales expected to increase in the future at an annual rate of about 4 percent (EPA, February 1978, p. 9). Therefore, the effects of the guidelines on employment and plant utilization would tend to be offset, so that there would tend to be no net effects. If pesticides were not a growth industry, the potential for job and plant losses would be much greater.

Data limitation make it impractical to project the number of plant closures which might occur as a result of implementing the proposed guidelines. Indications are that small formulating plants and basic pesticide production plants are quite flexible, allowing them to make adjustments so that actual plant closures will be minimized.

Formulation plants have a great deal of flexibility since their operations are in essence a combination of mixing and packaging. Switching from formulating one active ingredient which might not be reregistered to an active ingredient (old or new) that is registered might require no more than cleaning and adjusting existing apparatus. The long leadtime of the generic standards approach to implementing the guidelines should allow sufficient opportunity for formulators to obtain new registrations of products with active ingredients that are registered or reregistered.

The small volume active ingredient producers would not, in most cases, be affected by the guidelines requirements for a period of up to 10 to 15 years. Goring (1977) uses a 20-year time horizon, including development time, to evaluate the expected return on investment in pesticide development. Assuming that this is the industry norm in terms of expected product life, then the development time, market time accrued to date, and the 10 to 15 years mentioned above would indicate that presently registered active ingredients may have achieved their original market life expectation before being asked to meet the proposed guidelines data requirements.

Plant closures are therefore not likely to occur in the near future. In the long run any such closures may not be distinguished from the normal turnover in an industry as dynamic as pesticide production. Furthermore, the industry is projected to grow at a rate of 4 percent or more according to current estimates by industry and other experts.

F. CONSUMER EFFECTS

Direct effects on consumers due to price increases on pesticides used by them have already beeb discussed above. This section of the report addresses overall impact upon consumer, i.e., direct and indirect combined, assuming all costs are passed on to the ultimate consumer.

As discussed above, average annual total costs of implementing the guidelines for home and garden uses equal $7.1-$10.5 million or $0.03-$0.05 per capita. If the costs for nonhome and garden uses of pesticides are added to these figures, the following cost impacts are projected on the average during the 1980's.

Incremental—$22-$23 million, $0.10 per capita.

Including data gaps—$71-76 million, $0.32 - $035 per capita.

These cost impacts, while significant, are quite small when compared to total consumer expenditures for goods and services ($1.2 trillion per year, currently). They are also small when compared to the overall costs of environmental cleanup and protection programs which are estimated to equal about $290 billion (over $1,300 per capita) for the decade 1976-85 (CEQ, 1977).

G. OTHER IMPACTS

The macroeconomic (GNP, inflation, employment, etc.) impacts of the guidelines are projected to be insignificant. Inpacts in the range of $100 to $125 million per year (0.008-0.01 percent of GNP) are clearly insignificant to the overall economy in terms of production, employment, inflation, savings, investment, etc. Impacts are significant only at the sector level and very often merely distributional rather than net overall impacts. Certain products or firms are disadvantaged compared to others, but on the average losses and gains would tend to be nearly equal.

Impacts on energy and other searce mineral resources are not likely to be significant. Overall pesticide production and use would remain largely unaffected thus no overall net effects would be expected. Problems would be solved generally by short term adjustments among producers and users of pesticides, apart from the minor use/small volume pesticide problem which would only be aggravated (not caused) by implementing the guidelines. Special research training and extension efforts may be needed to minimize these problems and are already in place to some extent.

Implementation of the guidelines as discussed in this report assumes that the various data requirements can be met by research and data gathering activities on a scale substantially above current levels, i.e., doubling. There are potential constraints on conducting the needed R. & D. in the time frames indicated. For example, there could be shortages in personnel and facilites to conduct requred toxicology and environmental effects research. The Office of Pesticide Programs is in the process of obtaining contractor effort to assist in evaluating this matter. This effort could be quite important inasmuch as demands for such research are increasing in other related program areas.

The testing industry should be anticipating the trend toward increased safety testing of chemicals from not only the Office of Pesticides, but also Office of Toxic Substances in EPA, Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), Consumer Product Safety Commission (CPSC), etc. The phasing of the proposed guidelines requirements over a period of more than 10 years will allow the testing industry opportunity to expand to fill the expected increase in demand for safety testing of chemicals.

The Office of Pesticide Programs intends to continue its policy of allowing registrants sufficient time to secure testing facilities when constraints exist. For reregistration, the registrants are allowed to continue to produce and market their products until the needed data are generated. The proposed guidelines are designed to generate data on scientific bases to evaluate the potentiasl risks of pesticide products. There is no administrative policy or statutory mandate that data requirements under FIFRA should be limited due to short term shortages in laboratory facilities when shoratages are fully expected to abate and cause no hardships on registrants.

The Agency is a member of the Interagency Regulatory Liaison Group (IRLG) composed of EPA, FDA, OSHA, and CPSC. Through the organization, coordination of testing requirements for chemicals across these agencies would be expected to ensure that priorities are established for the testing of chemicals.

VIII. LIMITATIONS OF ANALYSIS

This report of projected economic impacts from subparts B, D, E, and F, of the guidelines for registering pesticides under FIFRA is not in as great detail as would be preferred. Data bases are weak in several areas. While the guidelines are being proposed, further generation of data and analysis is being undertaken by the agency. Major limitations of the existing analysis are as follows:

1. Costs are projected on estimated average unit costs of tests which will vary in practice considerably around averages depending on the specific circumstances of proposed registrations of a pesticide product. Although best available data from private labs, pesticide producers, Government labs, EPA personnel, and consultants were utilized in making cost estimates, there is a high degree of uncertainty as to the actual average costs. This is particularly true because of opportunities for waiver of requirements which will occur on a case-by-case basis and opportunities for reducing requirements for minor use pesticides as provided for in proposed amendments to FIFRA under consideration by the Congress at the present time. During the period for which the guidelines are being proposed, EPA is conducting further analysis of the unit costs of the various tests and data requirements. Contractor support is planned for these efforts.

2. The analysis assumes that the various data requirements and tests can be met under the registration scenarios during the 1980's in the absence of significant constraints on generation

of such data and tests due to scarcities in laboratory facilities and/or analytical expertise. Limited data are presently available on the capacity of such research facilities and expertise. Inasmuch as implementation of the guidelines would result in substantial increases in pesticides R. & D., and limited data are available on the capacity of these industries to meet such requirements, the Agency is conducting an analysis of this matter, with contractor effort during the upcoming months.

3. Economic profile data are limited with respect to pesticide producers, formulators, and users, particularly the latter two groups. The analysis reflects economic impacts largely on an aggregate basis and on the average for these groups. It lacks detail with respect to specific impacted segments and categories, for which impacts may vary greatly. Some sectors or groups could be much more seriously affected than the average. For that reason, further analysis is being made of this matter also by the Agency with contractor effort. In addition, the Agency is specifically requesting input as to such impacts in connection with the proposed guidelines. Such inputs and comments will be taken account of in preparation of the final economic impact analysis.

4. The two scenarios for implementation of the guidelines in connection with a generic standards program during the 1980's provide only rough approximations of economic impacts during that period. It is possible at this time to project with precision the actual costs and impacts because such detailed plans over the period have not been prepared. Even if they were, they would be subject to considerable change due to the time period involved. The Agency believes that the two scenarios presented are indicative of the range of most likely implementation scenarios during the 1980's. No attempt was made to estimate economic impacts on an annual basis beyond the 1980's during which reregistration of existing pesticides would be expected to be completed.

5. Projections of the number of new active ingredients and formulations to be registered during the 1980's are mere linear projections from recent years. It is impossible that the estimate of 15 new active ingredients per year could be significantly underestimated or overestimated. The Agency is conducting further analysis of research and development trends in the pesticide industry, including financial outlook information. This analysis will be available during the upcoming months.

6. Impacts of the proposed guidelines on minor use pesticides as well as small volume active ingredients are analyzed in the current analysis but will be subjected to further analysis in the future. Particular attention will be paid to the availability of pesticides for minor uses and substitues for small volume active ingredients which may no longer be economic with full implementation of the guidelines over the decade of the 1980's. Further attention will be paid to potential plant closures and attendant economic and community impacts.

7. The current analysis does not consider economic impacts the guidelines could have upon the extent to which pesticide research and development and production activities are carried out in this country as compared to foreign nations. Attention will be focused on this matter as appropriate depending upon comments received on this analysis and further review the Agency has undertaken on this matter.

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Appendix A—Sources of Cost Estimates

The cost of a test or data submission described in the guidelines will generally vary with the product being tested. For this analysis, cost estimates for a typical product were sought. Sources of cost estimates include pesticide producers, private contract laboratories, government laboratories, and OPP personnel. Tables A-1 through A-5 list the sources of test costs used in this analysis. When several estimates for a single test were available, an average figure was derived. The costs used should not be interpreted as the figures for all products. They are only representative costs. For any single product the actual cost could be higher or lower than the costs provided.

Another point to be remembered is that the estimates will vary in accuracy depending on the degree to which the test is standardized. For example, the cost of a hydrolysis test in environmental chemistry will be more accurate than a field test in the fish and wildlife hazard area.

The analysis also includes estimates on the costs of tests under current practice. Some of these costs differ from the costs of tests as described in the guidelines. The costs under current practice were estimated by OPP personnel.

A-1

Sources of Cost Estimates for Product Chemistry Requirements under Guidelines

Guidelines Requirement	Estimated Cost ($)	Source(s) of Estimate: Private Lab(s)	Pesticide Producer(s)	Gov't. Lab(s)	OPP Personnel
Manufacturing Process Description (MUP)	1,100		X		X
Manufacturing Process Description (Form)	1,000		X		X
Theoretical Discussion (MUP and Form)	100		X		X
Development of Methodology for Analytical Assay (MUP)	60,000		X		X
Devlopment of Methodology for Analytical Assays (Form)	160,000				X
Develop of Methodology For Analytical Assay on Formulated Products Produced by Integrated System (Form)					
Sample Analysis (MUP and Form)	1,600		X		X
Physical/Chemical Properties (MUP and Form)	1,600		X		X

A-2

Sources of Cost Estimates for Environmental Chemistry Tests Under Guidelines

Guidelines Requirement	Estimated Cost ($)	Source(s) of Estimate: Private Lab(s)	Pesticide Producer(s)	Gov't. Lab(s)	OPP Personnel
Hydolysis	12,000	X	X	X	
Photodegradation	20,000	X	X	X	
Aerobic Soil Metabolism	29,000	X	X	X	
Anaerobic Soil Metabolism	29,000 [1/]	X	X	X	X
Araerotic Aquatic Metabolism	25,000	X	X	X	
Aerobic Aquatic Metabolism	25,000	X	X	X	
Effects of Pesticides on Microbes	28,000	X	X	X	
Effects of Microbes on Pesticides	28,000	X	X	X	
Activated Sludge Metabolism	15,000	X	X	X	
Leaching	10,000	X	X	X	
Volatility	7,500	X	X	X	
Adsorption/Desorption	7,500	X	X	X	
Water Dispersal	16,000	X	X	X	
Field Dissipation-Soil	29,000	X	X	X	
Field Dissipation-Water	21,000	X	X	X	
Forest Dissipation	50,000	X	X	X	
Combination & Tank Mix	9,000 [2/]		X		X
Long Term Study	20,000 [3/]				
Rotational Crop	20,000 [3/]	X	X	X	
Irrigated Crops	20,000	X	X	X	
Fish Accumulation	20,000	X	X	X	

1/ In addition to aerobic soil metabolism
2/ In addition to Field Dissipation-Soil
3/ Assume 4 crops

A-3

Sources of Cost Estimates for Special Chemistry Requirements under Guidelines

Guidelines Requirement	Estimated Cost ($)	Source(s) of Estimate: Private Lab(s)	Pesticide Producer(s)	Gov't. Lab(s)	OPP Personnel
Residue Analysis on Green Tobacco	50,000				X
Residue Analysis on Dry Tobacco	20,000 1/				X
Residue Analysis in Smoke Including Pyrolysis Products	80,000 2/				X

1/ In addition to residue analysis on green tobacco
2/ In addition to residue analysis on green and dry tobacco

A-4

Sources of Cost Estimates for Fish and Wildlife Hazard Tests under Guidelines

Guidelines Requirement	Estimated Cost ($)	Source(s) of Estimate: Private Lab(s)	Pesticide Producer(s)	Gov't. Lab(s)	OPP Personnel
Avian LD 50	1,500	X	X		
Avian Dietary LC50	2,000	X	X		
Mamalian Acute Toxicity	1,000				X
Avian Reproduction	24,000	X			
Small pen Study	12,000	X			X
Large Pen Study	25,000				X
Field Test	50,000				X
Fish Acute LC50	750	X	X		
Acute Toxicity to Aquatic Invertebrates	360	X			
Acute Toxicity to Estuarine & Marine Organisms		X			
Fish Reproduction or Invertebrate Life-cycle	11,500	X			
Fish Life-cycle	40,000	X			
Aquatic Organism Toxicity & Residue	20,000				X
Simulated or Actual Field Testing for Aquatic Organisms	200,000	X			X

Table A-5

Sources of Cost Estimates for Human and Domestic Animal Hazard Evaluations

Guidelines Requirement	Estimated Cost ($)	Sources of Estimate			
		Private Lab(s)	Pesticide Producer(s)	Gov't Lab(s)	OPP Personnel/ Consultant
Acute Oral	700	X	X		
Acute Dermal	650	X	X		
Acute Inhalation	750	X	X		
Primary Eye Irr.	550	X	X		
Primary Dermal Irr.	400	X	X		
Dermal Sensitization	400	X			
Acute Delayed Neurotoxicity	5,000				X
Subchronic Oral Dosing	75,000	X			
21-day Dermal Tox.	20,000				X
90-day Dermal Tox	25,000				X
Subchronic Inhalation	12,000				X
Subchronic Neurotoxicity	12,000				X
Chronic Feeding	150,000	X	X		
Oncogenicity	162,000	X	X		
Teratogenicity	30,000	X			X
Reproduction	30,000	X			
Mutogenicity	55,000	X			
Metabolism	14,000				X

APPENDIX B—MARKET SHARE PROFILE DATA

Table B-1

Cumulative Market Shares for Active Ingredients,
Not Including Various Salts and Esters Which Are Registered

Cumulative Percent of Sales by Type	Number of Active Ingredients 1/		
	Insecticides 2/	Herbicides 3/	Fungicides
10	2	1	1
20	3	2	2
30	5	3	3
40	7	4	5
50	10	8	7
60	16	14	12
65	20	18	15
70	24	22	
75	30	28	
80		33	
85		42	
90			
95			
100	420	410	240

1/ Does not distinguish the various salts and esters which are also registered except on the 100% of sales line.
2/ Includes nematicides
3/ Includes plant growth regulators

Table B-2

Selected Cumulative Market Shares for
Active Ingredients Including Associated Salts and Esters

Cumulative Percent of Sales by Type	Number of Active Ingredients (Sales Volume in Millions)			
	Insecticides 2/	Herbicides 3/	Fungicides	Total
65			20($72)	
70				
75	30($570)			
80				125($1,832)
85		75($1,190)		
90				
95				
100	420($760)	410($1,590)	240($110)	1070($2,460)

1/ Includes counts of salts and esters which are also registered.
2/ Includes nematicides
3/ Includes plant growth regulators

Table B-3

Average Sales Volumes for Active Ingredients

			Average Sales Per AI 1/ ($000's)
Insecticides			
Largest	30	AI's	19,000
Remaining	390	AI's	487
Total	420	AI's	1,810
Herbicides			
Largest	75	AI's	15,860
Remaining	335	AI's	1,195
Total	410	AI's	3,880
Fungicides			
Largest	20	AI's	3,600
Remaining	220	AI's	410
Total	240	AI's	460
Summation			
	125	AI's	14,650
	945	AI's	665
	1,070	AI's	2,300

1/ AI = Active Ingredient

APPENDIX C—DERIVATION OF COST FIGURES IN TABLES 17 AND 18

The cost of test data will vary with the chemical and with the anticipated use pattern. Generally, pesticides used in agriculture on food crops will require the most intensive and expensive data because of the potential human ingestion through residues and the more likely broader environmental impacts. A review of the tests outlined in the guidelines indicated that at the upper end, data costs would average $950,000 for pesticides with broad food crop uses. This figure would include the more expensive longer term feeding studies required for human hazard evaluation. At the lower end an average of $200,000 would be expended for all data required. This figure would generally not include the more expensive toxicology and environmental studies. Pesticides requiring data costing $200,000 would ordinarily not have food crop uses and would have more limited use patterns. The remaining pesticides with assorted use patterns would fall in the range $200,000 to $950,000, on the average. If the same approach were applied under current Agency practice, the range would be $150,000 to $700,000 (see tables C-2 and C-3).

Table C-1 provides estimates of the number of active ingredients expected to need the varying dollar amounts of data assuming that all currently registered products are considered. Figures are given in terms of both guidelines and current practice. The approach used to develop the breakdown was to apply the highest costs to the first 300-350 active ingredients, which would cover the pesticides use by the agricultural sector (see table C-2). Then the costs were reduced to the minimum levels in such a way as would provide a weighted average data cost which approximated the figures in the cost analysis of this report (see table C-3).

The figures in table C-1 must be adjusted to reflect the value of data which has been submitted to the Agency and would be acceptable under the guidelines. It was estimated in the cost analysis that 16 percent of the value of data required by the guidelines has been submitted to the Agency. In terms of the data cost of current practice, the data submitted would be 21 percent of the total value. Table C-4 provides the adjusted figures.

The figures in C-4 are then further adjusted to add in the cost of test data on formulations made from the active ingredients. The cost anlaysis indicated that for an active ingredient use in agriculture, the additional testing costs would add 25 percent under current practice and 40 percent under the guidelines. Table C-5 provides these adjusted figures.

These costs are then assumed to be incurred over a 4-year time period. Then 25 percent of the costs from table C-5 are used in tables 17 and 18 to provide the basis for calculating the annual expense to the pesticide industry.

Table C-1

Expected Cost of Data for Active Ingredients
Under A Generic Standard Scenario

Number of Active Ingredients		Cost of Data	
		Current Practice	Guidelines
		$ 000's	
First	150	700	950
Next	150	600	800
"	150	450	500
"	150	250	300
"	150	200	300
"	150	150	200
"	150	150	200
"	150	150	200
"	150	150	200
Last	110	150	200
Total	1,460		

Table C-2

Costs to Meet Guidelines, Current Practice, and
Data Gaps for Typical Agricultural Pesticide Active Ingredient

Guidelines Area	Costs			Percent of Data Cost Yet to Be Incurred	Cost of Data Yet to Be Incurred
	Current	Guidelines	Difference		
Product Chemistry	$ 57,000	$ 67,000	$10,000	50	$ 33,500
Environmental Chemistry	$225,000	$225,000	$ 0	95	$213,750
Fish and Wildlife	$ 50,000	$ 75,000	$25,000	90	$ 67,500
Human Hazard	$350,000	$600,000	$250,000	50	$300,000
Total	$682,000	$967,000	$285,000	64	$614,750

Table C-3
Costs to Meet Guidelines, Current Practice, and Data Gaps for Average Pesticide Active Ingredient, All Use Patterns

Guidelines Area	Costs			Percent of Data Cost Yet to Be Incurred	Cost of Data Yet to Be Incurred
	Current	Guidelines	Difference		
Product Chemistry + Special Chemistry	$ 57,000	$ 67,859	$10,000	50	$ 33,500
Environmental Chemistry	$131,228	$131,228	$ 0	95	$124,700
Fish and Wildlife	$ 9,475	$ 12,924	$ 3,449	95	$ 12,300
Human Hazard	$ 84,466	$169,267	$78,611	75	$125,000
Total	$282,169	$381,278	$92,060	79	$295,500

Table C-4
Expected Data Cost Subtracting Value of Data Already Submitted

Number of Active Ingredients		Cost of Data	
		Current Practice	Guidelines
		$ 000's	
First	150	550	800
Next	150	475	675
"	150	350	420
"	150	200	250
"	150	160	250
"	150	120	170
"	150	120	170
"	150	120	170
"	150	120	170
"	150	120	170
Last	110	120	170
Total	1,460		

Table C-5
Net Data Cost Including Data for Corresponding Formulations

Number of Active Ingredients		Cost of Data	
		Current Practice	Guidelines
		$ 000's	
First	150	685	1,120
Next	150	595	945
"	150	438	588
"	150	250	350
"	150	200	350
"	150	150	238
"	150	150	238
"	150	150	238
"	150	150	238
Last	110	150	238
Total	1,460		

APPENDIX D—BENEFITS TO BE DERIVED FROM GUIDELINES REQUIREMENTS AND RATIONALE FOR INCREMENTAL CHANGES

Table D-1

Benefits to be Derived from Guidelines Requirements and Rationale for Incremental Changes

Guidelines Subpart and Section	Benefit of Data Requirement	Comparison of Current Practice and Guidelines Requirements		Rationale for Incremental Guidelines Requirements
		When Required (No. of Chem./ Products)	Level of Data (Scope/Rigor)	
Product Chemistry				
Description of manufacturing process (163.61-4)	To assure the Agency that a thorough and diligent effort to anticipate ingredients (intentional and unintentional) has been made	Increase	Increase	Unintentional impurities may occur at any stage of manufacturing or packaging. A more complete process description is therefore needed. Some additional products are covered since some formulated products are produced themselves from formulated products.
Discussion of unintentional ingredients (163.61-5)	To anticipate impurities (e.g., dioxin in 2,4,5-T) which could create unreasonable risks to the environment	New	New	This is a new requirement added because of past experience with impurities such as dioxins and nitrosamines. This requirement would allow a review of potential risks which might occur because of unintentional ingredients in products.
Declaration and certification of ingredient limits (163.61-6)	Variance in the composition of a product outside of certain limits can reasonably be expected to change the efficacy and potential risk of products. The Agency intends to control this variance by registering only those products whose composition can be stably produced and maintained.	New	New	This is a new requirement added to allow the manufacturer to certify the limits on the levels of active ingredients, inerts, and impurities to be in compliance with the requirements to accurately label their products' composition.
Product analytical methods and data (163.61-7)	The Agency has need for methodologies (analytical or otherwise) to determine the kind and levels of ingredients in products. These methodologies are used in enforcement of FIFRA and in determining the registerability of pesticide products. Also, the Agency needs the results of these methodologies as applied to samples of the products for comparative purposes.	Increase	Increase	The "when required" has been increased to cover products reformulated from other formulated products since changes in the composition could occur. The level of rigor has been increased to reflect more current scientific methods of analytical chemistry. Also, analysis of five samples are now required as opposed to one before, to measure the variance of results likely to be obtained.
Physical and chemical properties (163.61-8).	Physical and chemical properties such as boiling point would be used to confirm the description of the manufacturing process; others would be used to evaluate hazard potential, such as flammability; and finally others such as odor would be helpful in identifying the causative agents in accidental poisoning.	Increase	Increase	This requirement has been extended to cover products reformulated from other formulations. An octanol/water partition coefficient has been added as a measure of a chemical's lipid solubility.
Special Chemistry Requirements				
Pesticides on tobacco (163.64-1)	Use of pesticides on tobacco does not require a tolerance or exemption from tolerance. Data are, however, needed to assess the exposure of man to pesticide residue upon the consumption of tobacco.	Same	Same	There are no changes over current requirements for this section.

Table D-1 (Cont'd)

Guidelines Subpart and Section	Benefit of Data Requirement	Comparison of Current Practice and Guidelines Requirements: When Required (No. of Chem./ Products)	Comparison of Current Practice and Guidelines Requirements: Level of Data (Scope/Rigor)	Rationale for Incremental Guidelines Requirements
Environmental Chemistry				
Physico-chemical degradation (163.62-7) - hydrolysis - photodegradation	Degradation studies are used to determine the rate of decomposition and identification of pesticide residues which are formed through the action of sunlight or water on a product. The fate of these residues help to evaluate the hazard potential of pesticides.	Same	Same	There are no changes over current practice for this section.
Metabolism (163.62-8) - aerobic soil - anaerobic soil - anaerobic water - aerobic aquatic - effects of microbes on pesticides - effects of pesticides on microbes - activated sludge	Pesticides introduced into the environment can be transformed by metabolic means. Metabolic processes can occur in soil and in water. Metabolism data are needed to evaluate the fate of pesticides in the environment under aerobic and anaerobic conditions in both soil and water. Additionally, pesticides may enter wastewater treatment facilities. It is necessary to evaluate the effects of pesticides on activated sludge use in treatment plants.	Same	Same	There are no changes over current practice for this section.
Mobility (163.62-9) - leaching - volatility - adsorption/desorption - water dispersal	Mobility studies are used to evaluate the movement of pesticide residues in the environment. Such movement may cause contamination of the food web (including nontarget crops), loss of useable land and water resources, and habitat loss for wildlife. Leaching, volatility, adsorption/ desorption, and water dispersal were selected as common measures of pesticide mobility.	Same	Same	There are no changes over current practice for this section.
Field dissipation (163.62-10) - soil - water - ecosystem - combination and tank mixes - long term study	Field studies determine pesticide dissipation and mobility in the environment which may differ from rates observed under laboratory conditions. Data from these studies are needed to assess the potential hazards for reentry into treated areas, residues in rotational crops, residues in the food web, and contamination of land and water resources.	Same	Same	There are no changes over current practice for this section.
Accumulation (163.62-11) - rotational crop - irrigated crop - fish - special studies	Pesticides introduced into the environment may enter and accumulate in food webs. Studies in this section will determine this accumulation in rotational crops, irrigated crops and fish.	Same	Same	There are no changes over current practice for this section.

Table D-1 (Cont'd)

Guidelines Subpart and Section	Benefit of Data Requirement	Comparison of Current Practice and Guidelines Requirements: When Required (No. of Chem./ Products)	Comparison of Current Practice and Guidelines Requirements: Level of Data (Scope/Rigor)	Rationale for Incremental Guidelines Requirements
Hazard Evaluation: Wildlife and Aquatic Organisms				
Avian single dose LD_{50} (163.71-1)	This test measures the single dose level of a pesticide which would produce mortality in birds. This is an input to evaluate the potential hazard to birds from a single ingestion of a pesticide or pesticide contaminated food.	Same	Same	There are no changes from current requirements for this test.
Avian dietary LC_{50} (163.71-2)	This test measures the dose level of a pesticide which would produce mortality in birds over a feeding period of several (5) days. These data are used to evaluate the hazard to birds of dietary exposure to pesticides.	Same	Same	There are no changes from current requirements for this test.
Mammalian acute toxicity (163.71-3)	This test measures the single dose level of pesticide which would produce mortality in wild mammals such as deer. These data are used to evaluate the potential hazard to wild mammals from a single ingestion of a pesticide or pesticide contaminated food.	Increase	Increase	Agency experience has identified additional insecticides for which these data are needed.
Avian reproduction (163.71-4)	This test measures the effects of exposure to pesticides on avian reproduction. Pesticides which persist in the environment have the potential to disrupt reproduction in birds. This test is an input to evaluate this hazard.	Increase	Same	Agency experience has identified additional insecticides, fungicides, and herbicides which are now thought to pose risk to avian reproduction.
Simulated and actual field testing (163.71-5)	Field testing provides data which more clearly identify potential hazard to birds and/ or mammals. This testing can answer questions raised by ambiguous results from laboratory testing, or it may be used to evaluate impacts on non-target species under actual pesticide use conditions.	Increase	Same	Agency experience has identified additional pesticides in all classes for which field testing data would provide a more supportable scientific basis for decision making.
Fish acute LC_{50} (163.72-1)	This test measures the pesticide concentration in water which will produce mortality in fish. These data are used to evaluate the potential hazard which pesticides entering water may cause to fish.	Increase	Same	Additional tests on formulated products are being required because of increasing concerns about the differences in toxicity among formulations which contain different inerts.
Acute toxicity to aquatic invertebrates (163.72-2)	This test measures the pesticide concentration in water which will produce mortality in aquatic invertebrates such as mayflies. These data are used to evaluate the impacts on invertebrate species, which, if affected, might disrupt the aquatic ecosystem.	Same	Same	There are no changes from current requirements for this test.

Table D-1 (Cont'd)

Guidelines Subpart and Section	Benefit of Data Requirement	Comparison of Current Practice and Guidelines Requirements		Rationale for Incremental Guidelines Requirements
		When Required (No. of Chem./ Products)	Level of Data (Scope/Rigor)	
Acute toxicity to estuarine and marine organisms (163.72-3)	This test measures the effects of pesticides in an estuarine or a marine environment. This is an input to evaluate the potential hazard of pesticides to fish, crab, shrimp, molluscs, etc.	Increase	Increase	The test proposed now includes the addition of marine fish. Additional products are to be tested because of the Agency's concern with plant effluents and run-offs.
Embryo-larvae and life-cycle studies of fish and aquatic invertebrates (163.72-4)	This test provides the Agency with data on the long term effects of pesticides on fish and other water inhabiting organisms.	Increase	Same	Additional chemicals will require this test primarily because of concern that disinfectants in waste water find their way into water bodies and have the potential for producing hazardous effects on fish and other aquatic organisms over a long period of time.
Aquatic organism toxicity and residue study (163.72-5)	This test will provide data on the effects on non-target organisms of pesticides applied to or expected to enter water bodies. Particular attention is paid to the build-up of pesticide residies in the aquatic food chain.	Increase	Same	The increase in the number of chemicals to be tested reflects the increasing concern over the build-up of persistant pesticides in the food chain.
Simulated or actual field testing for aquatic organisms (163.7]-6)	Field testing provides data which more clearly identify potential hazard to aquatic life than can sometimes be produced in a laboratory. When laboratory findings indicate potential risks, then field testing can provide data under actual environmental conditions which may confirm or refute the laboratory findings.	Increase	Same	Agency experience, especially with disinfectants, has indicated that a few additional chemicals would need this test.
Hazard Evaluation: Humans and Domestic Animals				
Acute studies (163.81-1, -2, -3) - acute oral toxicity - acute dermal toxicity - acute inhalation toxicity - primary eye irritation - dermal sensitization - acute delayed neurotoxicity	Data from these sections are used to determine the relative toxicity of compounds, how pesticides cause toxic effects, and the proper design for longer term studies. Other uses for this data include issuance of RPAR's, classification of pesticides for restricted or general use, and label warnings of hazard.	Increase	Increase	Increases in the scope or rigor of acceptable test protocols on scientific grounds are proposed for acute dermal toxicity and acute inhalation toxicity tests. The changes are to allow a better measure of the statistical significance of the test results. Tests are now required for acute oral and acute dermal toxicity when the technical grade active ingredient differs from the manufacturing-use product. These changes are to determine if the inert ingredients in the manufacturing-use product alters the toxicity. A requirement to measure the oral toxicity of the use dilution for some products used in the home was added because of concern over accidental poisonings in the home. Finally, all manufacturing-use products are proposed to be tested for dermal sensitization as opposed to a few under current practice. This change reflects a concern for pesticide production worker safety.

Table D-1 (Cont'd)

Guidelines Subpart and Section	Benefit of Data Requirement	Comparison of Current Practice and Guidelines Requirements: When Required (No. of Chem./ Products)	Comparison of Current Practice and Guidelines Requirements: Level of Data (Scope/Rigor)	Rationale for Incremental Guidelines Requirements
Subchronic testing (163.81-1, -2, -3, -4, -5) - subchronic oral dosing - subchronic 21-day dermal toxicity - subchronic 90-day dermal toxicity - subchronic inhalation toxicity - subchronic neurotoxicity	These sections provide data on results of repeated exposure through various routes. These data also serve to identify target organ and to establish dose levels for life-time or chronic studies. Finally these data are used to compare the toxicity of pesticides according to the route of exposure.	Increase	Increase	The 90-day dermal toxicity study is prepared to be newly added for pesticides which are purposely applied to human skin. Systemic toxicity effects can then be measured in similar fashion to a subchronic oral study. The 21-day dermal toxicity is proposed to cover more chemicals than under current practice because of increasing concern over applicator and worker exposure. The protocol for the subchronic inhalation has been expanded with a significant cost increase to cover inhalation exposures which are long or almost continuous. A subchronic neurotoxicity test has been newly added to obtain further data on those chemicals which produced nervous system effects in the acute delayed neurotoxicity test or other studies. Under current practice the longer term neurotoxocity effects are not now evaluated in a special study.
Chronic testing (163.83-1, -2, -3, -4) - chronic feeding study - oncogenicity studies - teratogenicity studies - reproduction study	These sections describe tests for detecting adverse effects from lifetime exposure to a pesticide. Focus is on detection of malignant and benign tumors, birth defects, fetotoxicity, decreased fertility, premature delivery, smaller offspring, and other chronic effects. These tests are required on pesticides likely to be ingested through various routes of exposure by the human population.	Increase	Increase	The scope and rigor of the chronic testing area is proposed to be increased to reflect more stringent scientific standards accepted today. These standards include additional test animals and dosing levels, and longer test periods to provide increased statistical reliability and better data bases for extrapolation of the results.
Mutagenicity testing (163.84-1, -2, -3, -4)	These sections provide data on the mutagenic potential of pesticides. Through regulation, the Agency would decrease human exposure to chemicals shown to cause genetic mutations.	Increase	Same	Currently the Agency is requiring mutagencity testing on pesticides which may leave residues on food or feed crops. This section is proposed to be extended to cover additional pesticides to which humans may be exposed through routes other than food.
Special testing (163.85-1) - general metabolism study	These studies will provide data on how a pesticide moves, changes, or accumulates in the mammalian system. These data are designed to identify pesticide metabolites in mammals and provide a basis for evaluating the chronic effects of pesticides on humans. The metabolites formed in an animal system may differ from those formed in the environment. Metabolism studies are therefore needed in addition to the tests under environmental chemistry.	Increase	Same	Currently the Agency is requiring metabolism studies on pesticides which may leave residues on food or feed crops. This section is proposed to be extended to cover additional pesticides which humans may receive exposure through other routes. Exposure through non-food routes can also add a pesticide burden to the body.

APPENDIX E—EXCERPT FROM SECTION II-A IN PREAMBLE TO SUBPART F ENTITLED "TEST SUBSTANCE." THIS SECTION PROVIDES AN EXAMPLE OF ALTERNATIVE APPROACHES CONSIDERED IN DRAFTING THE PROPOSED GUIDELINES

The majority of the other tests in this proposal are subchronic and chronic studies, and the guidelines would generally require that they be performed with the technical grade of each active ingredient in the product. The decision to routinely require intermediate and long-term toxicity testing only on technical chemicals is based both on the Agency's experience in reviewing the toxicity of the ingredients of pesticide products and on economic considerations.

Pesticide products contain many different kinds of ingredients. Every pesticide contains at least one pesticidally "active ingredient," which by definition produces toxic or behavior-altering effects in one or more organisms exposed to the chemical. The ordinary commercial production of pesticidally active ingredients usually introduces manufacturing impurities or byproducts which may also be toxic. Other chemical substances called "inert ingredients" [1] are deliberately added during the formulation of an end-use product to improve the usefulness of the pesticide, reduce its hazard to users, to dilute the chemicals, to stabilize the ingredients, and for several other reasons. An "inert ingredient" may bring its own impurities or may react with other ingredients or packaging materials to produce new impurities. Finally, some pesticides are somewhat unstable and over time may partially degrade to form still more substances.

[1] The term "inert ingredient" is defined by FIFRA § 2(m) and refers to any ingredient in a product which is pesticidally inactive. These substances, however, are not necessarily nontoxic, nor are they necessarily biologically or chemically inert.

EPA recognizes that any of the ingredients in a pesticide product could be toxic to man or other beneficial organisms. Experience, however, has shown that, with some notable exceptions, the active ingredients and associated manufacturing impurities are of greatest concern. These impurities, together with the active ingredient, make up what is usually considered the "technical chemical." Thus, testing the technical chemical is consistent with that experience.

Comments already received recommend that subchronic and chronic studies be performed on technical chemicals and on each formulated product, as well. The basis for this recommendation is that ingredients in an end-use product, other than the active ingredient, may pose risks to man and the environment. Moreover, testing the formulated product would detect effects caused by the synergistic (or other) interaction of different ingredients. These effects would not be evaluated by testing each ingredient separately.[2] Another alternative has been proposed: That data from subchronic and chronic tests be derived from tests with each ingredient in a pesticide product, not merely the active ingredients. This alternative would require testing of each deliberately added inert ingredient in a product, and possibly each impurity. This testing scheme, however, would not identify toxic effects resulting from the interaction of two different ingredients.

EPA considers both of these alternatives economically prohibitive. Over 30,000 formulated products are registered; they contain approximately 1,450 different active ingredients, and a comparable number of deliberately added inert ingredients. By extending the data requirements for subchronic and chronic studies to include data from tests on formulated products, the Agency would increase the number of required tests twentyfold. Extending the data requirements from active ingredients to deliberately added inert ingredients would double the amount of testing required in this proposal. If testing of impurities were also required, the amount of testing would triple. Such test requirements would not only strain the national capacity to perform toxicological assays, but would also place an extraordinarily heavy burden on the industry.[3] Moreover, EPA is not persuaded that the additional data generated by routine testing of inert ingredients, impurities, and end-use products would significantly improve the quality of EPA's decisionmaking. Consequently, proposed § 163.80-3(b)(2)(iv) states that additional testing of these substances would be required only on a case-by-case basis. The Agency invites public comment on whether the subchronic and chronic data requirements should be extended to include routine testing of substances other than the technical grade of active ingredients.

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[2] The acute oral, dermal, and inhalation toxicity studies, § 163.81-1 through -3, are designed to detect some synergistic or other interactions between ingredients in a pesticide. Under these sections, data must be submitted on the LD_{50} and LC_{50} of each active ingredient in a pesticide product, as well as the manufacturing-use or formulated product, itself. If the toxicity of the product exceeds the additive toxicity of the individual active ingredients, further testing may be required to determine the source of the enhanced toxicity. Such additional toxicity could result either from the independent toxicity of an inert ingredient or from the interaction of ingredients in the formulation.

[3] See the economic impact analysis report on these proposed regulations (FR citation).